
CMS Manual System

Pub. 100-16 Medicare Managed Care

Department of Health &
Human Services (DHHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 91

Date: AUGUST 7, 2009

SUBJECT: Chapter 3, "Medicare Marketing Guidelines"

I. SUMMARY OF CHANGES: As part of the implementation of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008, CMS has revised the Medicare Marketing Chapter to include the latest provisions and clarifications in the current guidance. This revision replaces Chapter 3, "Medicare Marketing Guidelines."

NEW / REVISED MATERIAL = EFFECTIVE DATE: August 7, 2009

IMPLEMENTATION DATE: August 7, 2009

Disclaimer for manual changes only: Normally, red italic font identifies new material. However, because this release is a complete rewrite of the chapter, normal text font is used for this revision.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)

(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	3/Medicare Marketing Guidelines
R	3/Appendix 1/Summary of Benefits
R	3/Appendix 2/Attestation Form for Translated Non-English Materials or Alternate Materials
R	3/Appendix 3/Plan Sponsor Website Must Use Chart
R	3/Appendix 4/Model File and Use Certification Form

III. FUNDING: No additional funding is currently provided by CMS; contractor activities are to be carried out within their own FY 2009 and/or future operating budgets determined by the organizations.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

*Unless otherwise specified, the effective date is the date of service.

Chapter 3 – Medicare Marketing Guidelines

For Medicare Advantage Plans, Medicare Advantage Prescription Drug Plans, Prescription Drug Plans, and 1876 Cost Plans

Table of Contents

(Rev. 91, 08-07-09)

10	Introduction
20	Definitions
30	Plan Sponsor Responsibilities
30.1	Limitations on Distribution of Marketing Materials
30.2	Co-branding Requirements
30.2.1	Co-branding with network providers
30.2.2	Co-Branding with State Pharmaceutical Assistance Programs (SPAP)
30.3	Provider Name in Plan’s Name or Downstream Entity’s Name
30.4	Use of Data from Medigap Issuers
30.5	Plan Sponsor Responsibility for Subcontractor Activities and Submission of Materials for CMS Review
30.5.1	Multiple Organization Marketing Pieces Created by Agents
30.6	Anti-Discrimination
30.7	Requirements for Plan Sponsors with Non-English Speaking Populations or Populations with Special Needs
30.8	Compliance with Section 508 of the Rehabilitation Act
30.9	Materials Required for Program Start-up
30.9.1	Required Materials in Enrollment Package (Pre-Enrollment)
30.9.2	Required Materials for New and Renewing Members at Time of Enrollment and Annually Thereafter
30.9.3	Required Ongoing Materials for New and Renewing Members
30.10	Hold Time Messages
30.11	Use of the Medicare Name
30.12	Referral Programs
30.13	Privacy and Confidentiality
30.14	Plan Ratings Information from www.medicare.gov
40	General Marketing Requirements
40.1	Marketing Material Identification Number
40.1.1	Marketing Material Identification Number for Non-English or Alternate Materials
40.2	Font Size Rule
40.3	Footnote Placement
40.4	Reference to Studies or Statistical Data
40.5	Prohibited Terminology/Statements

- 40.6 Statements Related to Claim Forms and Paperwork
- 40.7 Logos/Tag Lines
- 40.8 Identification of All Plans in Materials
- 40.9 Marketing to Beneficiaries of Non-Renewing Medicare Plans
- 40.10 Product Endorsements/Testimonials
- 40.11 Customer Service Hours of Operation
- 40.12 Use of TTY Numbers
- 40.13 Additional Materials Enclosed with Required Post Enrollment Materials
- 40.14 Marketing of Multiple Lines of Business
 - 40.14.1 Multiple Lines of Business-General Information
 - 40.14.2 Multiple Lines of Business - Exceptions
 - 40.14.3 Multiple Lines of Business – Television
 - 40.14.4 Multiple Lines of Business – Internet
 - 40.14.5 Multiple Lines of Business - HIPAA Privacy Rule
 - 40.14.6 Multiple Lines of Business- Non-Benefit/Service-Providing Third Party Marketing Materials
- 40.15 Providing Materials in Alternate Formats/Media Types
- 40.16 Standardization of Plan Name Type
- 50 Marketing Material Types and Applicable Disclaimers
 - 50.1 Guidance and Disclaimers that Apply to All Materials
 - 50.1.1 Federal Contracting Statement
 - 50.1.2 Benefit Changes
 - 50.1.3 Additional Guidance Applicable to All PFFS Plan Materials
 - 50.1.4 Additional Guidance for SNP Materials
 - 50.1.5 Plan Sponsor Responsibility -Disclaimer When Providing Third Party Marketing Materials
 - 50.1.6 Plan Sponsor Responsibility -Disclaimer for Materials that are Co-branded with Providers
 - 50.1.7 Applicable Disclaimers for the Marketing of Educational Events
 - 50.2 Specific Guidance Applicable to General Advertising Materials
 - 50.2.1 Radio Advertisements
 - 50.2.2 Television Advertisements
 - 50.3. Applicable Disclaimer When Benefits Are Mentioned
 - 50.3.1 Disclaimers on Advertisements and Invitations to Sales/Marketing Events
 - 50.3.2 Disclaimers Applicable to Advertising that Promotes a Nominal Gift
 - 50.4 Explanatory Marketing Materials
 - 50.5 Guidance and Disclaimers Applicable to Explanatory Marketing Materials
 - 50.5.1 Required Access Information Disclaimers
 - 50.5.2 Enrollment Limitations
 - 50.5.3 Explanatory Marketing Materials that Mention Benefit and Plan Premium Information
 - 50.5.4 Pharmacy Network Limitations
 - 50.5.5 Online Enrollment Center Disclaimer
 - 50.5.6 Eligibility Requirement Disclaimers
 - 50.5.7 Availability of Medicare Subsidy Information
 - 50.5.8 Availability of Alternate Formats

50.5.9 Additional Guidance for Preferred Provider Organization (PPO) Plans

50.5.10 Additional Guidance for PFFS Plans

50.5.11 Additional Guidance for 1876 Cost Plans

50.6 Plan Sponsor Mailing Statements on Envelopes/Mailing Itself

60 Specific Guidance on Required Documents

60.1 Summary of Benefits (SB)

60.2 Part D ID Card Requirements

60.3 ID Card Information for MA PPOs and PFFS

60.4 Directories

60.4.1 Pharmacy Directories

60.4.2 Provider Directories

60.4.3 PCP and Specialty Directories

60.4.4 Combined Provider/Pharmacy Directory

60.4.5 Mailing the Provider/Pharmacy Directory to Addresses with Multiple Members

60.4.6 Changes to Provider Network

60.5 Formulary and Formulary Change Notice Requirements

60.5.1 Abridged Formulary

60.5.2 Comprehensive Formulary

60.5.3 Changes to Printed Formularies

60.5.4 Formularies Provided on Plan Websites

60.5.5 Other Formulary Documents

60.5.6 Provision of Notice to Beneficiaries Regarding Formulary Changes

60.5.7 Provision of Notice to Other Payers Regarding Formulary Changes

60.6 Explanation of Benefits

60.7 Annual Notice Of Change (ANOC) and Evidence of Coverage (EOC)

70 Promotional Activities, Events, and Outreach

70.1 General Guidance about Promotional Activities

70.2 Nominal Gifts

70.2.1 Exclusion of Meals as a Nominal Gift

70.2.2 Nominal Gift Disclaimer

70.3 Unsolicited E-mail Policy

70.4 Marketing through Unsolicited Contacts

70.5 Specific Guidance on Telephonic Contact

70.5.1 Specific Guidance on Third-party Contact

70.6 Outbound Education and Verification Calls to All New Enrollees

70.7 Educational Events

70.7.1 Educational Event Disclaimer

70.8 Health Fairs and Health Promotional Events

70.8.1 Additional Sole Sponsor Policies

70.8.2 Additional Multiple-Sponsor Policies

70.8.3 Provider Participation in Health Fairs

70.9 Marketing/Sales Events

70.9.1 Additional Guidance for Marketing Events in the Provider Setting

70.9.2 Plan Activities and Materials in the Health Care Setting

70.9.3 Provider-Based Activities

70.9.4 Provider Affiliation Information

- 70.9.5 SNP Provider Affiliation Information
- 70.9.6 Comparative and Descriptive Plan Information
- 70.9.7 Comparative and Descriptive Plan Information Provided by a Non-Benefit/Service Providing Third-Party
- 70.9.8 Providers/Provider Group Websites
- 70.10 Personal/Individual Marketing Appointments
 - 70.10.1 Scope of Appointment
 - 70.10.2 Beneficiary Walk-ins to a Plan or Agent/Broker Office or Similar Beneficiary-Initiated Face-to-Face Sales Event
- 70.11 Specific Guidance on Outreach to Dual Eligible Members
 - 70.11.1 Guidance on Dual Eligibility
 - 70.11.2 Guidance for Dual Eligible Outreach Program
 - 70.11.3 Outreach Submission Requirements
 - 70.11.4 CMS Review/Approval of Outreach Process
 - 70.11.5 Reviewing New Outreach Programs
 - 70.11.6 Reviewing Previously Approved Outreach Programs
- 70.12 PFFS Plan Provider Education and Outreach Programs
 - 70.12.1 PFFS Plan Staff Requirement for Assisting Providers
 - 70.12.2 PFFS Plan Terms and Conditions of Payment Contact and Website Fields in HPMS
- 70.13 Requirement that All Plans Give Beneficiaries Notice of Sales Event Cancellations
- 80 Special Guidance on Telephonic Scripts and Activities**
 - 80.1 Customer Service Call Center Requirements
 - 80.1.1 Pharmacy Technical Help Call Center
 - 80.1.2 Coverage Determinations and Appeals Call Center
 - 80.1.3 Required Inbound Informational/Customer Service Telephone
 - 80.2 Enrollment via Inbound Telephone
 - 80.3 Telephonic Sales Scripts
- 90 Guidance on the Marketing Review Process**
 - 90.1 Plan Sponsor Responsibilities
 - 90.2 Material Submission Process
 - 90.2.1 Mandatory Use of Marketing Material Review Checklists for All Documents
 - 90.3 Material Disposition Definitions
 - 90.3.1 Approved Disposition
 - 90.3.2 Disapproved Disposition
 - 90.3.3 Deemed Disposition
 - 90.3.4 Withdrawn Disposition
 - 90.3.5 Additional Service Area (SA)/Low Income Subsidy (LIS) Materials
 - 90.4 Alternate Format
 - 90.5 Time Frames for Marketing Review
 - 90.5.1 45-Day Standard Review Period
 - 90.5.2 10-Day Model Review Period
 - 90.6 File & Use Program Overview
 - 90.6.1 Materials Qualified for the File & Use Submission
 - 90.6.2 Materials Not Qualified for File & Use Submission
 - 90.6.3 Restriction on the Manual Review of File & Use Eligible Materials

- 90.6.4 Loss of File & Use Certification Privileges
- 90.7 Additional Guidance for CMS Provided Language/Materials
 - 90.7.1 Standardized Language
 - 90.7.2 Standardized Materials
 - 90.7.3 Model Materials
- 90.8 Template Materials
 - 90.8.1 Submission of Template Materials
- 90.9 Expedited Review Process for Template Annual Renewal Materials
 - 90.9.1 Eligibility for Participation in the Expedited Process
 - 90.9.2 Submission of Templates under the Expedited Review Process
- 90.10 Submission of Non-English (*Alternate Formats) Materials
- 90.11 Acceptable Formats
- 90.12 Submissions Outside of HPMS
- 90.13 Requirements for Joint Enterprise for PDPs and Regional Preferred Provider Organizations (RPPOs)
- 90.14 Multi-Contract Entities (MCEs)
- 90.15 Review of Materials in the Marketplace
- 90.16 File & Use Retrospective Monitoring Reviews
 - 90.16.1 Template Materials Quality Review and Reporting of Errors
- 90.17 Specific Guidance on the Submission of Websites for Review
- 90.18 Special Guidance on the Submission of SB and ANOC/EOC
- 90.19 Specific Guidance on the Submission of General Advertising Materials
- 90.20 Materials Not Subject To Review
- 100 Special Guidance on Plan Sponsor Websites
 - 100.1 Plan Sponsor Website Requirements
 - 100.2 Organization Website Content
 - 100.2.1 Pharmacy Access Information
 - 100.2.2 Provider Access information
 - 100.2.3 Specific Guidance Regarding Grievance, Coverage Determination (including Exceptions) and Appeals Website Requirements
 - 100.2.4 Low Income Subsidy (LIS) Website Premium Summary Table for People Receiving Extra Help
 - 100.3 Required Links
 - 100.3.1 Prohibited Links
 - 100.4 Required Disclaimers on Websites
 - 100.5 Enrollment via the Internet
 - 100.5.1 Required Materials When Online Enrollment is Utilized
- 110 Specific Guidance about Value-Added Items and Services
 - 110.1 Definition of Value-Added Items and Services (VAIS)
 - 110.2 VAIS Examples
 - 110.3 CMS Review of VAIS Materials
 - 110.4 Further Requirements on VAIS
 - 110.5 Value Added Items and Services Provided to Employer Groups
- 120 Guidance on Marketing and Sales Oversight and Responsibilities
 - 120.1 Compliance with State Appointment Laws
 - 120.2 Plan Reporting of Terminated Agents

- 120.3 Agent/Broker Training and Testing
- 120.4 Agent/Broker Use of Marketing Materials
- 120.5 Agent/Broker Compensation
 - 120.5.1 Definition of Compensation
 - 120.5.2 Compensation Types
 - 120.5.3 Compensation Cycle (6-Year Cycle)
 - 120.5.4 Specific Guidance for Developing and Implementing Compensation Strategy
 - 120.5.5 Compensation Calculation
 - 120.5.6 Specific Guidance for Recovering Compensation Payments (Charge-backs)
 - 120.5.7 Guidance for the 2010 Plan Year and Beyond
 - 120.5.8 Third Party Marketing Entities
- 120.6 Activities That Do Not Require the Use of State-Licensed Marketing Representatives
- 130 Guidelines Applicable to Employer/Union Group Health Plans
- 140 Special Guidance for Medicare Medical Savings Account (MSA) Plans
 - 140.1 General Advertising Materials
 - 140.2 Explanatory Marketing Materials Requirements
 - 140.3 Outbound Education and Verification Calls
- 150 Use Of Medicare Mark For Part D Plans
 - 150.1 Authorized Users for Medicare Mark
 - 150.2 Use of Medicare Prescription Drug Benefit Program Mark on Items for Sale or Distribution
 - 150.3 Approval to Use the Medicare Prescription Drug Benefit Program Mark
 - 150.4 Restrictions on Use of Medicare Prescription Drug Benefit Program Mark
 - 150.5 Prohibition on Misuse of the Medicare Prescription Drug Benefit Program Mark
 - 150.6 Mark Guidelines
 - 150.6.1 Mark Guidelines - Negative Program Mark
 - 150.6.2 Mark Guidelines - Approved Colors
 - 150.6.3 Mark Guidelines on Languages
 - 150.6.4 Mark Guidelines on Size
 - 150.6.5 Mark Guidelines on Clear Space Allocation
 - 150.6.6 Mark Guidelines on Bleed Edge Indicator
 - 150.6.7 Mark Guidelines on Incorrect Use
 - 150.7 Part D Standard Pharmacy ID Card Design

Appendices

Appendix 1: Summary of Benefits

Appendix 2: Attestation Form for Translated Non-English Materials or Alternate Materials

Appendix 3: Plan Sponsor Website Must Use Chart

Appendix 4: Model File & Use Certification Form

10 - Introduction

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

These Marketing Guidelines reflect the Centers for Medicare & Medicaid Service (CMS) current interpretation of the marketing requirements and related provisions of the Medicare Advantage (MA) and Medicare Prescription Drug Plan (PDP) rules (Chapter 42 of the Code of Federal Regulations, Parts 422 and 423). These Guidelines are for use by Medicare Advantage organizations offering MA plans and MA prescription drug (MA-PD) plans, and Prescription Drug plans (PDPs). Some of the provisions in this chapter also have applicability to Section 1876 Cost contracts for materials and activities aimed at Medicare beneficiaries, Medicare age-ins, and their caregivers. These marketing guidelines are not applicable for the Program of All-Inclusive Care for the Elderly (PACE) plans since PACE plans are governed by separate guidance which is not discussed in this document.

NOTE: The provisions in this chapter provide sub-regulatory operational guidance. While most of the guidance in this chapter may not apply directly to Medicare 1876 Cost Plans, CMS encourages cost contractors to follow instructions that are addressed to MA-only plans. Cost plans that mention Part D as an optional supplemental benefit in their marketing materials should follow MA-PD guidance.

The scope of the term marketing, as used in the Medicare statute and CMS regulations extends beyond the public's general concept of advertising materials. Pursuant to 422.2260 and 423.2260 of Chapter 42 of the Code of Federal Regulations, marketing materials include any informational materials targeted to Medicare beneficiaries which are defined in §20.

In addition, CMS' definition of marketing extends beyond materials to include activities, conducted by the plan sponsor or an individual or organization on behalf of the plan sponsor, that include steering, or attempting to steer, a potential enrollee towards a plan, or limited number of plans, for which the individual or entity performing marketing activities expects compensation directly or indirectly for such marketing activities. As such, CMS' authority for marketing oversight extends to include a range of different marketing materials and activities.

It is important to note that the marketing guidance set forth in this document is subject to change as communication technology and industry marketing practices continue to evolve. Moreover, the examples of marketing materials and promotional activities given in these Guidelines are not all-inclusive. Plan sponsors should apply the principles outlined in these Guidelines to all relevant decisions, situations, and materials. Any new rule-making or interpretative guidance (e.g., call letter or Health Plan Management System (HPMS) guidance memoranda) may update the marketing guidance provided here, and sound judgment and consultation with CMS Account Managers should be used in situations where new guidance updates the guidance provided in this document. Specific questions regarding a marketing material or any marketing practice should be directed to the plan's Account Manager or designated Marketing Reviewer.

20 - Definitions

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2, 422.4, 423.4, 42260, 423.2260, 422.2264, 423.2264, 422.68, 423.2268, 422.2272, 423.2272

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

Advertising

Advertising materials are primarily intended to attract or appeal to a potential plan sponsor enrollee. Advertising materials contain less detail than other marketing materials, and may provide benefit information at a level to entice a potential enrollee to request additional information.

Examples of advertising materials include:

- Television Ads;
- Radio Ads;
- Outdoor Advertising (ODA) such as billboards or signs attached to transportation vehicles;
- Banner and Banner-like Ads;
- Print Ads (newspaper, magazine, flyers, brochures, posters, church bulletins);
- Post Stands and Free Standing Inserts (newspapers, magazines);
- Event Signage;
- Internet Advertising;
- Pharmacists' promotional buttons;
- Window Stickers;
- Counter Tents; and
- Direct Mail that does not include enrollment forms, such as postcards, self mailers, home delivery coupons, and reply cards.

Assisting in Enrollment

Assisting in enrollment consists of assisting a potential enrollee with the completion of an application and/or objectively discussing characteristics of different plans to assist a potential enrollee with appraising the relative merits of all available individual plans, based solely on the potential enrollee's needs. As used in these guidelines, the phrase "assisting in enrollment" does not apply to assistance being provided by an individual or entity receiving direct or indirect compensation from the company with which the beneficiary is considering enrolling.

Banner and Banner-Like Advertisements

Banner advertisements are typically used in television ads, and flash information quickly across a screen with the sole purpose of enticing a prospective enrollee to contact the plan sponsor for more information. A “banner-like” advertisement is usually in some media other than television (for example, outdoor advertising, and internet banner ads) and is intended to be very brief and to entice someone to call the plan sponsor or to alert someone that information is forthcoming.

Co-Branding

Co-branding is defined as a relationship between two or more separate legal entities, one of which is an organization that sponsors a Medicare plan. The plan sponsor 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 plan sponsor 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 sponsor has with CMS.

Corporate Website

An organization’s web page may include information on the organization’s mission, history, contact information, products and services.

NOTE: All plans offering Part D are required to have a website. A web address is an address that is typed into the web browser, also known as a URL (Universal Resource Locator). A web link is a shortcut within a website or web page that connects the user to another location on the Internet. A web page is a single element of a website, usually an HTML-based document exclusively dedicated to a specific product (e.g., MA-PD plan or PDP).

Cost Plan

A plan operated by a Health Maintenance Organization (HMO) or Competitive Medical Plan (CMP) in accordance with a cost-reimbursement contract under Section 1876(h) of the Social Security Act.

Direct mail

Direct mail should possess one or more of the following characteristics: (1) pertains to rules or benefits of existing coverage or any other type of coverage offered, (2) contains more than three pages of content, and/or (3) has a salutation to a specific individual.

Education

Informing a potential enrollee about an MA or PDP in an unbiased way that does not steer, or attempt to steer, that enrollee toward a specific plan or limited number of plans. This definition is

detailed in 42 CFR 422.2268 and 42 CFR 423.2268 and excludes any plan specific activities or promotions during an educational event.

Educational Event

Educational events are defined by the way in which an event is marketed to the Medicare beneficiary. An event hosted by the plan or an outside entity is considered an educational event if the event is advertised to beneficiaries as “educational.”

The intent of this guidance is not to preclude plans from educating beneficiaries about their products rather it is to ensure that events that are advertised as “educational” comply with CMS’ requirements. More specifically, plans may provide education at a sales or marketing event, but may not market or sell at an educational event.

Educational events may not include any sales activities such as the distribution of marketing materials or the distribution or collection of plan applications.

Explanatory Marketing Materials

Explanatory marketing materials are a subset of marketing materials primarily intended to explain the benefits, operational procedures, cost sharing, and/or other features of a plan sponsor to current members or to those considering enrollment. Explanatory marketing materials are further subdivided into enrollment materials, pre-enrollment marketing materials and post-enrollment marketing materials, all of which are defined in §20.

Enrollment Materials

Enrollment materials are materials used to enroll or disenroll from a plan, or materials used to convey information specific to enrollment and disenrollment issues such as enrollment and disenrollment forms.

NOTE: Plans Sponsors should reference Chapter 2 of the Medicare Managed Care Manual, and Chapter 3 of the Prescription Drug Benefit Manual for model enrollment forms and notices.

Field Marketing Organization (FMO)

An intermediate entity, such as a “Field Marketing Organization” (FMO) or similar type entity that has been retained to sell a plan’s Medicare products on its behalf.

Health Plan Management System (HPMS)

Is a web-enabled information system that serves a critical role in supporting the implementation and ongoing operations of the Medicare Advantage program, and Medicare Prescription Drug program. HPMS and its software modules are used to collect and receive data.

Joint Enterprise

A Joint Enterprise is a group of organizations that are State licensed as risk-bearing entities that jointly enter into a single contract with CMS to offer a Regional Preferred Provider Organization (RPPO) or PDP in a multi-State region. The participating organizations contract with each other to create a single “Joint Enterprise” and are considered an “entity” for purposes of offering a RPPO or PDP.

Local Plans

A Local Plan is offered by a legal entity that is not a regional or National 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.

The term Plan is utilized in these guidelines to refer to one or all of the following Medicare Products: MA plans, MA-PD plans, PDP plans, and 1876 Cost Plans.

NOTE: PDPs cannot offer a local plan.

Marketing

Steering, or attempting to steer, a potential enrollee towards a plan, or limited number of plans. “Assisting in enrollment” and “education” do not constitute marketing.

CMS’ authority for marketing oversight extends to include a range of different marketing materials and activities. While not an exhaustive list, the following would fall under CMS’ purview per the definition of marketing:

- General audience materials such as general circulation brochures, direct mail, newspapers, magazines, television, radio, billboards, yellow pages, or the Internet;
- Marketing representative materials such as scripts or outlines for telemarketing or other presentations;
- Presentation materials such as slides and charts;
- Promotional materials such as brochures or leaflets, including materials for circulation by third parties (for example, physicians or other providers);
- Membership communications and communication materials including membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees;
- Letters to members about contractual changes; changes in providers, premiums, benefits, plan procedures, etc.;

- Membership or claims processing activities (for example, materials on rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or annual notification information); and
- The activities of a plan sponsor's employees, independent agents or brokers, subcontracted FMOs or other similar type organization that is contributing to the steering of a potential enrollee towards a specific plan or limited number of plans, and may receive compensation directly or indirectly from a plan sponsor for marketing activities.

Marketing Materials

The definition of marketing materials, as used in CMS regulations and these guidelines extends beyond the public's general concept of advertising materials. Pursuant to 42 CFR 422.2260 and 42 CFR 423.2260, marketing materials include any informational materials targeted to Medicare beneficiaries which:

- Promote the plan sponsor, or any MA or Part D plan offered by the plan sponsor;
- Inform Medicare beneficiaries that they may enroll, or remain enrolled in, an MA or Part D plan offered by the plan sponsor;
- Explain the benefits of enrollment in an MA plan or Part D plan or rules that apply to enrollees; and
- Explain how Medicare services are covered under an MA or Part D plan, including conditions that apply to such coverage.

Medicare Advantage (MA) Organization

An organization that is a public or private entity organized and licensed by a State as a risk-bearing entity that is certified by CMS as meeting the requirements to offer an MA plan.

Medicare Advantage Prescription Drug (MA-PD) Plan

An MA plan that provides qualified prescription drug coverage.

Model Document

For certain beneficiary informational documents, CMS has provided model language, which when used without modification, except within bracketed areas, entitles the plan sponsor to a shorter review period or to submission under File & Use as outlined in §90.6.1. The use of CMS model documents is optional; however, plans that choose to create their own pieces must be sure to include all information that is in the model document.

Multi Contract Entities (MCE)

A designation available for plan sponsors that have multiple MA/PDP contracts with CMS. Being designated as an MCE allows plans to submit template materials to CMS that are representative of all or a selection of the plan sponsors' contracts. The plan sponsors' Account Manager has the ability to approve requests for MCE designation once a plan sponsor requests the designation. Please note that, in most instances, MCE has replaced the designation of Multi-Regional Teams (MRTs)/Multi-Contract Groups (MCGs) and if a plan has already attained an MRT/MCG status no action is needed to convert it to MCE.

National Plans:

- **Prescription Drug Plans (PDPs):** The term "national plan" means a PDP sponsor that, at a minimum, offer plans in each of the 34 PDP regions that include the 50 States and the District of Columbia. PDP sponsors that offer plans in more than the minimum 34 PDP regions (i.e., those that include the 50 States, the District of Columbia, and one or more territories) are also considered national plans. PDPs sponsored by a Joint Enterprise, can also use the term "national" if the Joint Enterprise offers plans, at a minimum, in all 34 PDP regions that include the 50 States and the District of Columbia. (Refer to Federal Register Vol. 70 FR 13398).
- **Medicare Advantage and Medicare Advantage Prescription Drug Plans (MAs/MA-PDs):** The term "national plan" means a Medicare Advantage Organization (MAO) that offers MA/MA-PD plans in each of the 26 MA regions that include the 50 States and the District of Columbia. MAOs that offer MA/MA-PD plans in more than the minimum 26 regions (i.e., those that include the 50 States, District of Columbia, and one or more territories) are also considered national plans.

Nominal Value

Any promotional activities or items offered by plan sponsors, including those that will be used to encourage retention of members, must be of nominal value. "Nominal Value" is currently defined as an item worth \$15 or less, based on the retail purchase price of the item.

Outdoor Advertising (ODA)

Marketing material intended to capture the attention of an audience passing the outdoor display (e.g., billboards, signs attached to transportation vehicles) and to influence them to request more detailed information on the product being advertised.

Part C Program

The abbreviated term used to describe Medicare Advantage Program.

Part D Program,

The abbreviated term used to describe the Medicare Prescription Drug Program.

Part D Sponsor or Part D plan sponsor

A Part D sponsor means an MAO that offers an MA-PD plan, a PDP sponsor offering a PDP, or an 1876 Cost Plan offering qualified prescription drug coverage.

Plan

Refers to the plan benefits being offered by a MA, MA-PD, PDP, 1876 Cost and Employer Group Waiver plan.

NOTE: For purposes of this document the term “plans” will be utilized to describe all plans types unless otherwise noted in the guidance.

Plan Sponsor

The term “plan sponsor” is utilized in these guidelines to refer to the entity that has a contract with the Federal Government to offer one or all of the following Medicare Products: MA plans, MA-PD plans, PDPs, and 1876 Cost Plans.

NOTE: For purposes of this document the term “plan sponsor(s)” will be utilized to describe all organizational/plan types unless otherwise noted in the guidance.

Pre-Enrollment Marketing Materials

A subset of explanatory marketing materials, pre-enrollment materials (e.g., sales scripts, direct mail that includes an enrollment form, sales presentations) are generally used by prospective enrollees to decide whether or not to enroll in a plan. Pre-enrollment materials may contain plan rules and/or benefits information. Pre-enrollment marketing materials include but are not limited to:

- Sales scripts/sales presentations;
- Direct mail that includes an enrollment form;
- Sales presentation materials; and
- Summary of Benefits.

Post-Enrollment Marketing Materials

Subsets of explanatory marketing materials, post-enrollment materials are those materials used by a plan sponsor to convey benefits or operational information to enrolled plan members. Post-enrollment marketing materials include but are not limited to:

- All notification forms, letters and sections of newsletters that are used to communicate with the individual on various membership operational policies, rules, and procedures;
- Annual Notice of Change (ANOC);
- Enrollment Letters;
- Evidence of Coverage (EOC);
- Pharmacy Directory;
- Provider Directory;
- Formulary;
- Member ID card;
- Grievance, coverage/organization determination, and appeals letters;
- Exceptions process letters; and
- Member handbook.

Promotional Activities

Activities performed by a plan, or by an individual or organization on a plan's behalf, to inform current and potential enrollees of the products available. Promotional Activities typically provide a higher level of detail than general advertising.

Regional Plans

- **Prescription Drug Plan (PDP):** A regional PDP sponsor offers PDP plans that serve one or more entire PDP region(s), but not all 34 PDP regions that include the 50 States and the District of Columbia.
- **MA/MA-PD Regional Plans:** A MA or MA-PD regional plan is a coordinated care plan structured as a Preferred Provider Organization (PPO) that serves one or more entire MA region(s) but not all 26 MA regions that include the 50 States and the District of Columbia.

Sales Person

The term "sales person" is used in these guidelines to define an individual who markets and/or sells products for a single plan sponsor or numerous plan sponsors and includes internal sales force, brokers, agents, Field Marketing Organization (FMOs), and all other individuals, entities, and downstream contractors who may be utilized to market and/or sell on behalf of a plan sponsor.

Standardized Language

Language developed by CMS or other Federal agencies which is mandatory for use by the plan sponsor and cannot be modified.

State Pharmaceutical Assistance Program (SPAP)

Under Part D, an SPAP is a State program which provides financial assistance for supplemental prescription drug coverage for Part D eligible individuals.

Template Materials

Template materials are any marketing materials that includes placeholders to be populated by variable elements.

Value Added Items and Services

Value Added Items and Services (VAIS) are non-benefit items and services provided to a plan sponsor's enrollees. An item or service is classified as a VAIS if the cost, if any, incurred to the plan sponsor in providing the item or service, is solely administrative. A cost is not automatically classified as administrative simply because it is either minimal or non-medical. The cost, if any, must be intrinsically administrative; the cost must cover only such items as clerical or equipment and supplies related to communication (such as phone and postage), or database administration (such as verifying enrollment or tracking usage).

Note that this definition does not require that VAIS be health-related. A VAIS is not a benefit since no direct medical or pharmaceutical cost is incurred to the plan sponsor in providing the VAIS.

30 - Plan Sponsor Responsibilities

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

30.1 - Limitations on Distribution of Marketing Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262(a), 423.2262(a), 422.2260, 423.2260

A plan sponsor is prohibited from advertising outside of its defined service area unless such advertising is unavoidable. For situations in which this cannot be avoided (e.g., advertising in print or broadcast media with a national audience or with an audience that includes some individuals outside of the service area, such as a MSA (Metro Statistical Area) that covers two regions), plan sponsors are required to disclose clearly their service area.

30.2 - Co-branding Requirements

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

CMS permits plan sponsors to enter into co-branding arrangements. Plan sponsors doing so must comply with requirements in 42 CFR 422.2268 and 423.2268 (see §30.2.1 and §30.2.2). The following guidelines should be followed in the case of a co-branding arrangement:

- To ensure that CMS is made aware of any such relationships, the plan sponsor must inform its CMS Account Manager of any co-branding relationships at the time that the plan sponsor begins to input their plan benefit information (Plan Benefit Package - PBP) into the Health Plan Management System (HPMS). The HPMS PBP module will allow plan sponsors to indicate whether they are co-branding.
- Any changes in, or newly formed, co-branding relationships during the year should be communicated by the plan sponsor to its CMS Account Manager. The plan sponsor should also input this information in HPMS prior to marketing its new relationship. The plan sponsor should also remove any reference to the former co-branding partner(s) from its marketing materials.
- It is the plan sponsor's responsibility to ensure that its co-branding partner(s) also adhere(s) to all applicable CMS policies and procedures.
- The plan sponsor should attest that its co-branding partners were provided with these Marketing Guidelines and that the co-branding partners agree to follow these guidelines with respect to all marketing materials related to the plan sponsor.

In addition, plan sponsors are permitted to display the names and/or logos of non-provider entities not having substantially similar names and/or logos of a network provider or providers on all marketing materials, including the member identification card.

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

30.2.1 - Co-branding with Network Providers

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

In addition to the above requirements, plan sponsors are prohibited from displaying the names and/or logos of co-branded network providers on the plan sponsor's member identification card, unless the provider names, and/or logos are related to the member selection of specific provider/provider organization (for example, physicians, hospitals). This prohibition extends to entities

and/or co-branding partners with a substantially similar name and/or logo of a network provider or providers. The plan sponsor's contracted network providers are not considered co-branding partners.

Plan sponsors that choose to co-brand with network providers on other marketing materials are required to include the following language below all co-branding names and/or logos of provider co-branding partners on all other marketing materials:

“Other <Pharmacies/Physicians/Providers> are Available in Our Network”.

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

30.2.2 - Co-Branding with State Pharmaceutical Assistance Programs (SPAP)

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

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

States have asked if they can choose which plan sponsors to co-brand with, or if they must offer to co-brand with all plan sponsors. CMS believes that SPAPs should offer co-branding of materials, including the identification card, to all plan sponsors covering the service area of the SPAP. Whether a plan sponsor chooses to co-brand with the SPAP, or not, is completely up to the plan sponsor. Also, if a plan sponsor approaches the State to co-brand, the SPAP may do so. It should be noted that both the SPAP and the Part D plan sponsor should notify the plan's Account Manager in advance of the co-branding arrangement and must agree to adhere to all applicable Medicare Marketing Guidelines.

States have also asked whether it would be discriminatory if the SPAP, during its education and outreach campaign, informed the beneficiary which plan sponsors have agreed to co-brand. We do not believe that this would discriminate against other plan sponsors, as long as all plan sponsors 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 plan sponsors equal opportunity to co-brand with them and is

providing the same benefits for all beneficiaries regardless of the co-branded plan sponsors, 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.

30.3 - Provider Name in Plan's Name or Downstream Entity's Name

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

Plan sponsors whose legal or marketing names include the names of network providers, or whose downstream entities' legal or marketing names include the names of network providers, are required to include the following language below all names and/or logos of network providers on all of their marketing materials:

“Other <Pharmacies/Physicians/Providers> are Available in Our Network.”

The plan sponsor, its downstream entities, and its network providers, whether through marketing materials or other communications, may not imply that the network provider is endorsed by CMS, or that their products or services are Medicare-approved.

30.4 - Use of Data from Medigap Issuers

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

If a Medigap issuer chooses to sponsor an MA plan MA-PD plan or PDP, it is permitted to use its existing enrollment information from its Medigap plans to market its MA or Part D plan to its Medigap enrollees, to the extent permitted by the HIPAA Privacy Rule and other applicable Federal or State privacy laws. However in doing so, it should market to all of its members and not just a subset of its existing Medigap enrollees and must follow §70.10.1 requirements regarding scope of appointment.

Due to the nature and relationship of Medicare Supplement and MA/PDP product options, if during the course of an outbound call for a Medicare Supplement product the beneficiary initiates interest in an MA or PDP product, then that MA or PDP product may be discussed, as long as the call is recorded, including the beneficiary-initiated request for MA or PDP information.

30.5 - Plan Sponsor Responsibility for Subcontractor Activities and Submission of Materials for CMS Review

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

422.504 (h)(1), 422.504(h)(2)(i), 423.505(h)(1), 423.505(h)(2)(i), 422.2262, 423.2262

Plan sponsors that contract with CMS are responsible for all activities undertaken by their subcontractors on their behalf, including, but not limited to, all materials used that meet CMS' definition of a marketing material, all sales activities, and any and all scripts used to facilitate a sale.

CMS must review all applicable marketing materials prepared by a plan sponsor's sub-contractor(s) excluding marketing materials for employer/unions enrollees. Marketing materials may not be submitted directly by the third party to CMS; rather materials must be submitted directly by the plan sponsor that contracts with CMS (i.e., the MA organization or PDP sponsor offering the plan being marketed). It is the responsibility of the plan sponsor to ensure that all applicable materials created by a third party meet the requirements as outlined in these guidelines prior to their submission into HPMS. When a sub-contractor wants to use material previously approved by CMS, it must inform the plan sponsor. To that end, it is the responsibility of the plan sponsor to have a system in place to account for and control the materials that are being utilized by all third party contractors.

Refer to §130 of this chapter, Chapter 9 of the Medicare Managed Care Manual, and Chapter 12 of the Prescription Drug Benefit Manual.

30.5.1 - Multiple Organization Marketing Pieces Created by Agents

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

422.2262, 423.2262

This section provides specific guidance with regard to agents/brokers who create customized advertising materials that include plan information for multiple organizations. These guidelines require that all marketing materials be reviewed and approved by CMS prior to use in the marketplace. In addition, third party marketing materials, including materials created by agents/brokers, must also be submitted to the plan sponsor prior to use for review and approval and follow the guidance in §§30.5 and 120.4. Materials that are generic in nature and do not discuss content specific to plan benefits, cost-sharing or include the plan names will not require review and approval. Generic materials may reference the different product types (e.g., MA Plan, MA-PD Plans, Cost Plan, PDPs) offered by the agent. [NOTE: This guidance is not applicable to employer group health plan materials; refer to §130 of this chapter. In addition you can refer to §20.3.2.1.1 of Chapter 9 of the Medicare Managed Care Manual, and §20.3.2.1.1 of Chapter 12 of the Prescription Drug Benefit Manual.

30.6 - Anti-Discrimination

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.110, 422.2268(c), 423.2268(c)

Plan sponsors may not discriminate based on race, ethnicity, religion, gender, sexual orientation, disability, health status, or geographic location within the service area. All items and services of a plan sponsor are available to all eligible beneficiaries in the service area with the following exceptions:

- Certain products and services may be made available to enrollees with certain diagnoses (e.g., medication therapy management program for individuals with chronic illnesses or medically necessary coverage provisions);
- Enrollment in the low income subsidy, as there may be additional eligibility standards; and
- Beneficiaries with End Stage Renal Disease (ESRD).

Plan sponsors may not engage in discriminatory practices such as targeting marketing to beneficiaries from higher income areas or implying that plans are available only to seniors rather than to all Medicare beneficiaries. (The exception to this guidance is plan sponsors offering SNPs for which targeted enrollment for dual-eligible, institutionalized, or an individual having severe or disabling chronic conditions is permitted.)

30.7 - Requirements for Plan Sponsors with Non-English Speaking Populations or Populations with Special Needs

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264(e), 423.2264(e)

Plan sponsors should make marketing materials available in any language that is the primary language of more than ten percent of a plan sponsor's PBP service area. Additionally, call centers must be able to accommodate non-English speaking/reading beneficiaries. Plan sponsors should have appropriate individuals and translation services available to call center personnel to answer questions for non-English speaking beneficiaries that may have questions regarding the plan sponsor's offerings.

In addition, basic enrollee information must be made available to individuals with disabilities (for example, visually impaired). Plan sponsors must make sure information about their benefits is accessible and appropriate for Medicare beneficiaries who have disabilities.

Plan sponsors will be subject to verification monitoring review and penalties for violation of CMS policy. In addition to verifying the accuracy of non-English marketing materials through monitoring review, CMS will also periodically conduct marketing review of non-English materials on an "as needed" basis. If materials are found inaccurate or do not convey the same information as the English version, plan sponsors may not distribute materials until revised materials have been approved. Plan sponsors should refer to Appendix 2 (Attestation Form for

Translated Non-English or Alternate Materials). In addition, refer to section 90.10 for information on how to submit non-English or alternate materials via HPMS.

30.8 - Compliance with Section 508 of the Rehabilitation Act

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. § 794 (d)), as amended by the Workforce Investment Act of 1998 (P.L. 105-220), August 7, 1998

All plan sponsors are required to have an internet website that is compliant with web-based technology and information standards for people with disabilities as specified in Section 508 of the Rehabilitation Act. (Refer to Section 100 for details.)

30.9 - Materials Required for Program Start-up

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.111, 423.128, 422.2262, 423.2262

At a minimum, the following materials (if applicable) must be reviewed and approved (and/or appropriately submitted to CMS under File & Use):

- Website Content;
- Summary of Benefits;
- Provider Directory;
- Pharmacy Directory (Part D sponsors only);
- Comprehensive or Abridged Formulary (Part D sponsors only);
- Member Identification Card;
- Enrollment Form (see Enrollment Disenrollment Guidance); and
- Enrollment Notices (see Enrollment Disenrollment Guidance).

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

30.9.1 - Required Materials in Enrollment Package (Pre-Enrollment)

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.111, 423.128

When a beneficiary is provided marketing materials that include an enrollment form, the following information listed below should also be included. This, in total, represents an “Enrollment Kit”. When a plan sponsor utilizes an online enrollment, it must make these materials available electronically (for example via website links) to the member prior to the enrollment request being completed and submitted.

- A cover letter. Including the plan’s toll-free customer service telephone number, a TTY telephone number, customer service hours of operation, and a physical or post office address. The letter must indicate that beneficiaries may contact 1-800-MEDICARE (1-800-633-4227), or visit <http://www.medicare.gov> for more information about Medicare benefits and services including general information regarding the health or Part D benefit. The cover letter may include website URL for the plan sponsor.
- Enrollment instructions and forms.
- Written explanation of the plan’s grievance, coverage/organization determination (including exceptions) and appeals processes, including the differences between the processes and when it is appropriate to use each.
- Written notice that by law, plan sponsors can choose to not renew their contract with CMS and CMS may also refuse to renew the contract, thus resulting in a termination or non-renewal. This may result in termination of the beneficiary’s enrollment in the plan. In addition, the plan sponsor may reduce its service area and no longer offer services in the area where the beneficiary resides.
- Written notice on Low Income Subsidy (LIS), “People with limited incomes may qualify for Extra Help to pay for their prescription drug costs. If eligible, Medicare could pay for seventy five (75) percent of drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify will not be subject to the coverage gap or a late enrollment penalty. Many people are eligible for these savings and don’t even know it. For more information about this Extra Help, contact your local Social Security office or call 1-800-MEDICARE (1-800-633-4227), 24 hours per day, 7 days per week. TTY users should call 1-877-486-2048.”
- Information about their plan or (plans’) ratings information on <http://www.medicare.gov>. CMS will provide additional information, for sponsors to use in providing this information.

Plan sponsors have the option of including the following materials in pre-enrollment distribution and must make them available upon request.

- Pharmacy Directory (Part D sponsors only);
- Provider Directory;

- Comprehensive or Abridged Formulary (Part D sponsors only); and
- Summary of Benefits.

30.9.2 - Required Materials for New and Renewing Members at Time of Enrollment and Annually Thereafter

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.111, 423.128, 422.2264, 423.2264

The following materials must be distributed to a beneficiary and/or prior to the effective date of enrollment or within ten (10) calendar days of the receipt of the enrollment request or by the last day of the first enrollment month, whichever occurs first and annually thereafter. For example: plan sponsors are required to send the existing year's ANOC/EOC if the new members have an effective date of November 1 or December 1. This document must be provided to all new enrollees no later than ten calendar days of receipt of CMS confirmation of enrollment, or by the last day of the first enrollment month whichever occurs first. During the same time these members must also receive the ANOC/EOC for the upcoming plan year.

- Combined ANOC/Evidence of Coverage (ANOC/EOC);
[NOTE: Except Dual Eligible SNPs; refer to §60.7]
- Comprehensive Formulary or Abridged Formulary including information on how the beneficiary can obtain a complete formulary (Part D sponsors only);
- Combined Provider/Pharmacy Directory (Optional);
[NOTE: For all plan types except PDPs]
- Pharmacy Directory (For all plan sponsors offering a Part D benefit);
- Provider Directory (All plan types except PDPs);
- Membership Identification Card (required only at time of enrollment and as needed or required by plan sponsor post-enrollment); and
- Summary of Benefits (may be sent to all members annually but is not required; must be available to all members upon request)

30.9.3 - Required Ongoing Materials for New and Renewing Members

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.128(e)

Only those plan sponsors offering Part D must provide their enrollees an Explanation of Benefits (EOB) on at least a monthly basis for those months in which the enrollees use their Part D benefits. Refer to §60.6 for more information about the EOB.

30.10 - Hold Time Messages

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268 (f) and 423.2268(f)

Hold time messages (recorded information played to caller while waiting on hold) within telephone scripts must only discuss health-related features and other operational or general information (e.g., hours of operation, flu shot reminders). Scripts for hold time messages must be submitted for review and approval. Hold time messages may not include information on non-health related services (e.g., financial service information).

30.11 - Use of the Medicare Name

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 1140 of the Social Security Act

Under Section 1140 of the Social Security Act, 42 U.S.C. 1320b–10, it is forbidden for any person to use words or symbols, including “Medicare”, “Centers for Medicare and Medicaid Services”, “Department of Health and Human Services”, “Health and Human Services”, in a manner that would convey the false impression that the business or product is approved, endorsed, or authorized by Medicare or any other government agency. This rule extends to downstream contractors who may be directly or indirectly involved in marketing Medicare plans. Plan sponsors should ensure that their subcontractors are not using the Medicare name in a misleading manner. Refer to §150 for additional guidance on the Use of Medicare Name for Part D plans.

30.12 - Referral Programs

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

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

- A plan sponsor can ask for referrals from active members, including names and addresses, but cannot request phone numbers. Plan sponsors can then use this information to solicit by mail;

- Any solicitation for leads, including letters sent from plan sponsors to members cannot announce that a gift will be offered for a referral;
- Plan sponsors may not use cash promotions as part of a referral program; and
- Plan sponsors may offer thank you gifts that are worth \$15 or less, based on the retail purchase price of the item, (e.g., thank you note, calendar, pen, key chain) when an enrollee provides a referral as a result of a plan’s solicitation for referrals. These thank you gifts are limited to one gift per member, per calendar year.

30.13 - Privacy and Confidentiality

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.118, 422.752(a)(4), 423.136, 423.752(a)(4)

Plans and providers are responsible for following all Federal and State laws regarding confidentiality and disclosure of patient information to plan sponsors for marketing purposes. This obligation includes compliance with the provisions of the HIPAA privacy rule and its specific rules regarding uses and disclosures of beneficiary information. In addition, plan sponsors are subject to sanction for engaging in any practice that may reasonably be expected to have the effect of denying or discouraging enrollment of individuals whose medical condition or history indicates a need for substantial future medical services (i.e., health screening or “cherry picking”).

30.14 - Plan Ratings Information from www.medicare.gov

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264(a)(4), 423.2264(a)(3)

The Medicare program rates how well plan sponsors perform in different categories (for example, detecting and preventing illness, ratings from patients, patient safety and customer service). Plan sponsors must provide information about their plan or plans’ ratings information to current and prospective enrollees by referring them to <http://www.medicare.gov>, by including it in their pre-enrollment packets, and by making it available upon request. Information from <http://www.medicare.gov>, may not be altered in any way. CMS will provide additional information for plan sponsors to use in providing this information to current and prospective enrollees.

40 - General Marketing Requirements

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

40.1 - Marketing Material Identification Number

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262, 422.2264, 423.2264

Plan sponsors are required to place a unique marketing material identification number on all marketing materials. This information will allow CMS to track the plan sponsor's marketing material within the marketplace, and address beneficiary inquiries and/or complaints should they arise. This number is also used to identify and track materials in HPMS.

CMS requires a specific format for this identifier to allow immediate recognition of the document and/or advertisement as an approved marketing material. The Material ID can be any series of alphanumeric characters but must begin with the plan sponsor's contract number, also known as the "S/H/C/M/R" number, followed by an underscore. For example "S1234_" followed by numbers or letters chosen at the discretion of the plan sponsor, and a place-holder for the CMS approval date (the date that appears on the CMS approval notice).

This system allows each material to be identified by the specific plan sponsor, while also allowing the plan sponsor the freedom to develop its own filing system for its materials. The contract number and unique material identification number must be printed on the front of the Summary of Benefits (SB), and the Evidence of Coverage (EOC). The Material ID must be entered into HPMS in the same manner that it appears on the marketing material (i.e., "S1234_0021").

The PDPs and MA-PD plans must include the CMS contract number and PBP number on the membership identification card, as well as other required information as outlined in the Medicare Marketing Guidelines. Because of these requirements, the marketing materials identification number is not needed on the ID card. File & Use materials will not require a place holder for the CMS material approval date, since File & Use materials are not subject to a prospective marketing review. The Material ID and CMS approval date (for materials that do not qualify for File & Use) must be placed on every marketing material with the exception of the membership identification card, television and radio ads, outdoor advertisements, and banner or banner-like ads (including Internet banner ads). The Material ID should be positioned in the lower left- or lower right-hand corner of the material and be in twelve (12)-point font.

40.1.1 - Marketing Material Identification Number for Non-English or Alternate Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264(e), 423.2264(e)

Non-English or alternate materials must utilize the same tracking number as their English counterparts. When submitting the materials, plan sponsors must utilize the proper dropdown menu in HPMS to designate that they are non-English versions. Please reference the MA Marketing Module User Guide or PDP Marketing Module User Guide for further guidance.

40.2 - Font Size Rule

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

All text included on materials, including footnotes, and internal tracking numbers, must be printed with a font size equivalent to or larger than Times New Roman 12-point.

EXCEPTIONS:

- If a plan sponsor publishes a notice to close enrollment (as required in the Enrollment and Disenrollment guidance) in the Public Notices section of a newspaper, the plan sponsor need not use 12-point font and can instead use the font normally used by the newspaper for its Public Notices section.
- Because neither CMS nor the plan sponsor has any control over the actual screen size shown on individuals' computer screens that can be adjusted by the user, for Internet marketing materials, the 12-point font requirement refers to how the plan sponsor codes the font for the Web page, not how it actually appears on the user's screen.

40.3 - Footnote Placement

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

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

40.4 - Reference to Studies or Statistical Data

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

Plan sponsors may refer to the results of studies or statistical data in relation to customer satisfaction, quality, or cost as long as specific study details are given. At a minimum, study details need to be included in the material (either in the text or as a footnote) along with the source and date. Upon submitting material to CMS for review, the plan sponsor must provide to CMS the study sample size and number of plans surveyed unless the study that is referenced is a CMS study. Plan sponsors should enter study comments in the HPMS marketing material transmittal comments section.

- Plan sponsors are prohibited from using study or statistical data to directly compare their plan to another plan in marketing materials.
- If a plan sponsor uses study data that includes aggregate marketplace information on several other plans, they will not be required to submit data on all plan sponsors included

in the study. However, the study details, such as the number of plans included, must be disclosed.

- Plan sponsors referencing a CMS study should include reference information (publication, date, page number) in the HPMS Marketing Material Transmittal comments field. For non-CMS sponsored studies, plan sponsors are to submit the sample and number of plans surveyed in the HPMS marketing material transmittal comments.
- Additional information may be requested by the Account Manager or CMS marketing reviewer to help in facilitating the review of submitted materials.

40.5 - Prohibited Terminology/Statements

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

To ensure accurate and fair marketing by all plan sponsors, CMS prohibits the distribution of marketing materials that are materially inaccurate, misleading, or otherwise make material misrepresentations.

Plan sponsors may not:

- Misrepresent themselves, their plans, or the benefits and services covered by their plans;
- Claim within their marketing materials that they are recommended or endorsed by CMS, Medicare, or the Department of Health & Human Services (DHHS). Section 1140 of the Social Security Act, 42 U.S.C. §1320b-10, prohibits the use of the Department's name and logo, the agency's name and marks, and the word "Medicare" or "Medicaid" in a manner which would convey the false impression that such item is approved, endorsed, or authorized by CMS or DHHS, or that such person has some connection with, or authorization from, CMS or DHHS;
- Use absolute superlatives (e.g., "the best," "highest ranked," "rated number 1") unless they are substantiated with supporting data provided to CMS as a part of the marketing review process; and
- Plan sponsors are prohibited from comparing their organization/plan(s) to another organization/plan(s) by name unless they have written concurrence from all plan sponsors being compared. This documentation must be included when the material is submitted for review.

Plan sponsors may:

- State that the plan sponsor is approved for participation in Medicare programs and/or that it is contracted to administer Medicare benefits;

- Use the term “Medicare-approved” to describe their benefits and services within their marketing materials; and
- Use qualified superlatives (e.g., “one of the best,” “among the highest rank”).

40.6 - Statements Related to Claim Forms and Paperwork

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

If a piece of material addresses the issue of claim forms or paperwork, plan sponsors may indicate that their plan involves relatively little paperwork such as:

- Virtually no paperwork; or
- Hardly any paperwork.

Given the nature of the Part C and D program it would be misleading to suggest that there are no forms or paperwork involved. Plan sponsors cannot say:

- No paperwork;
- No claims or paperwork/no complicated paperwork; and
- No claim forms.

40.7 - Logos/Tag Lines

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268(o), 423.2268(o)

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

For plan sponsors with an existing investment in a company logo/product tag line, CMS will permit “grandfathering” of company logos/product tag lines established before January 28, 2005.

40.8 - Identification of All Plans in Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

When plan sponsors submit multiple separate and distinct bids and PBPs to cover the same region/service area, there is no requirement that all Medicare plans offered by the plan sponsor be identified in all marketing materials. At their discretion, plan sponsors may identify or mention more than one plan in a single marketing piece so long as there is a distinction made among marketed plans.

40.9 - Marketing to Beneficiaries of Non-Renewing Medicare Plans

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

Plan sponsors may market directly to beneficiaries of former Medicare plans that have chosen not to renew their contracts as long as the marketing does not begin until after the date the beneficiary has received the plan sponsor's non-renewal letter.

40.10 - Product Endorsements/Testimonials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264, 422.2268, 423.2268

In order not to be considered misleading, 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;
- The speaker must identify the plan sponsor's product by name;
- If an individual is paid to promote a specific product, this must be clearly stated (i.e., "paid endorsement");
- If an individual is paid to portray a real or fictitious situation, the ad must clearly state it is a "Paid Actor Portrayal;" and
- If a Medicare beneficiary offers endorsement, the individual must be a current enrollee of the plan sponsor offering the endorsement in their capacity as a Medicare beneficiary. The individual may not be an actor paid to portray a fictitious situation or a celebrity paid for his or her endorsement who also happens to be a Medicare beneficiary.

Product endorsements and testimonials cannot:

- Use quotes, anonymous or fictitious quotes by physicians, health care providers, and/or by Medicare beneficiaries not enrolled in the plan; and
- Use negative testimonials about other plans.

40.11 - Customer Service Hours of Operation

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.128(d)(1)

A plan sponsor must list the hours of operation for its customer service department in all places where a customer service phone number is provided. The toll-free number must cover, at a minimum, the entire region or area in which the plan sponsor offers the plan. Plan sponsors must also list the hours of operation for 1-800-MEDICARE any time the 1-800-MEDICARE number or Medicare TTY is listed (i.e., 24 hours a day/7 days a week).

Please note that the above guidelines apply to the customer service department telephone number and do not apply to any phone numbers included on advertising materials for persons to call for more information. In particular, advertisements that include an agent/broker's phone number should clearly indicate that calling the agent number will direct them to a licensed insurance agent/broker and that calling the customer service number will allow them to get plan information and enroll in the plan if they choose to. If an agent/broker phone number is listed then the plan sponsor's customer service phone number must also be included and all requirements for the customer service number in the marketing guidelines must be met (i.e., hours of operation, etc.).

40.12 - Use of TTY Numbers

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 501 and Section 504 of the Rehabilitation Act

The TTY numbers must appear in conjunction with any other phone numbers in the same font size and style as the other phone numbers. Plan sponsors can either use their own TTY number or State relay services, as long as the number included is accessible from TTY equipment. TTY customer service numbers are to be toll-free.

Exceptions:

- TTY numbers need not be included on ODA or banner/banner-like ads.
- In television ads, the TTY number need not be the same font size/style as other phone numbers since it may result in confusion and cause some prospective enrollees to call the wrong phone number. As an alternative, plan sponsors are allowed to use various

techniques to sharpen the differences between TTY and other phone numbers on a television ad (such as using a smaller font size for the TTY number than for the other phone numbers).

- TTY numbers are not required in radio or internet ads.

40.13 - Additional Materials Enclosed with Required Post Enrollment Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.111, 423.128

Plan sponsors are permitted to enclose certain additional materials as part of required post-enrollment material mailings (e.g., EOB, EOC, and ANOC) when specific requirements are met and followed. Any informational materials that are enclosed with the post-enrollment mailing must be:

- Related to benefit or plan operations as an enrollee in the plan (e.g., health education newsletters, Medication Therapy Management Program (MTMP) materials, and mail service forms for Part D drugs), and
- Distinctly separate (e.g., folded or different color pages) from the required document within the mailing envelope.

Any additional materials enclosed in the post-enrollment mailing must not include advertising materials (for example, materials advertising additional products such as Medigap by the plan sponsor). In addition, materials must comply with all relevant laws and regulations, including the Federal and any State anti-kickback statute.

40.14 - Marketing of Multiple Lines of Business

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

Plan sponsors may market other lines of business (both health-related and non health-related) in accordance with §§40.14.1 through 40.14.6.

40.14.1 - Multiple Lines of Business-General Information

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

Any plan sponsor's marketing materials sent to current members describing other health-related lines of business must contain instructions describing how individuals may opt out of receiving

such communications. Plan sponsors must make every effort to ensure that all individuals (including non-members) who ask to opt out of receiving future marketing communications are not sent such communications. For marketing multiple lines of business, plan sponsors must comply with the HIPAA rules in §40.14.5.

Plan sponsors that advertise multiple lines of business within the same marketing document must keep the organization's lines of business clearly and understandably distinct from the other products. Plan sponsors must make this distinction by utilizing different formatting styles that delineate the two products. For example, the document might highlight the name of the PDP product in bold and underlined font, and then include a paragraph to describe the product in "regular" font, next go on to highlight the name of a non-PDP product in bold and underlined font, and then include a paragraph describing the non-plan product in "regular" font. Also, if a plan sponsor advertises non-Medicare products with plan material, it must pro-rate any costs so that costs of marketing non-Medicare materials are not included as "plan-related" costs in the plan sponsor's bid to CMS.

40.14.2 Multiple Lines of Business - Exceptions

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

Plan sponsors must ensure that all marketing activities conform to the guidance provided in this document with regard to marketing through unsolicited contacts (§70.4).

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

The PDP sponsors must not include enrollment applications for non-Part D lines of business in any package marketing its plan products, as beneficiaries might mistakenly enroll in the other option thinking they are enrolling in a Part D benefit. If information regarding Part D products and non-plan lines of health related products is included in the same package, postage costs must be pro-rated so that costs of marketing non-Part D materials are not included as "plan-related" costs in its bids. Plan sponsors can combine information and enrollment application for non-competing lines of business (e.g., PDP and Medigap). However plan sponsors are not allowed to include enrollment applications within combined mailings that include competing product lines (e.g., MA-PD or MA and Medigap).

40.14.3 Multiple Lines of Business – Television

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

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

40.14.4 Multiple Lines of Business – Internet

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2260, 423.2260

Plan sponsors may market other lines of business concurrently with plan products on the Internet, though to avoid beneficiary confusion; plan sponsors must continue to maintain a separate and distinct section of their websites for plan information only. CMS will review plan sponsor's web pages to ensure that plans are maintaining the separation between Part D information and information on other lines of business.

40.14.5 - Multiple Lines of Business - HIPAA Privacy Rule

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

45 CFR Part 160

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

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

40.14.6 - Multiple Lines of Business- Non-Benefit/Service-Providing Third Party Marketing Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

A non-benefit/service-providing third party entity is an entity that contracts with a plan sponsor to perform responsibilities other than administering health care/prescription drug benefits or providing health care services/Part D drugs to Medicare beneficiaries. For the purpose of

marketing review, non-benefit/service providing third party entities are organizations or individuals that supply information to a plan sponsor's membership, which is paid for by the plan sponsor or the non-benefit/service-providing third party entity. An example of a non-benefit/service-providing third party could be a research firm that provides comparative data relating to Medicare Advantage /Part D plans or a company that provides electronic health records to providers or beneficiaries, CMS does not review marketing materials originated by non-benefit/service-providing third party entities.

Therefore, if a non-benefit/service-providing third party wishes to provide information to a plan sponsor's members, it must submit its materials to the plan sponsor, which in turn, may distribute the materials to its membership. It is the plan sponsor's responsibility to ensure that these marketing materials contain the disclaimer:

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

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

40.15 - Providing Materials in Alternate Formats/Media Types

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.64, 422.111, 423.48, and 423.128; Social Security Act [§1852(c) (1) and §1860D-4(a)(1)(A)]

The Social Security Act (§1852(c)(1) and §1860D-4(a)(1)(A)) and Medicare regulations describe how information must be provided to beneficiaries (in a clear, accurate, and standardized form), but do not limit the methods of transmittal. Refer to §50.5.8 for additional information on alternate formats.

As such, a plan sponsor may elect to provide materials to members or prospective members in a format other than traditional paper (e-mail, CD, DVD). With respect to materials that CMS deems mandatory, (the Summary of Benefits (SB), Annual Notice of Change (ANOC), Evidence of Coverage (EOC), and the Provider/Pharmacy Directory), plan sponsors have the option of contacting members to determine in what format they would like to receive the materials. Plan sponsors that choose this option must either contact members in writing (e.g., by letter, postcard, newsletter article) or via a recorded telephone conversation to determine whether they would like to receive a specific material or group of materials in another format. The plan sponsor must specify to the member the materials in question. If the plan sponsor does not receive a response from the member, then the plan sponsor must assume that the member wants to receive the information in hard copy. CMS may review plan electronic communication and portable media policies, procedures, systems, and documentation during monitoring and compliance visits.

In addition, plans electing to provide materials in an alternate format must:

- Provide hard copies of all member materials available to members upon request;

- Insure that the process is completely voluntary. Members must be informed of the option and be given the choice to opt-in. If a member no longer wishes to receive plan communications through electronic or portable media, they must be able to opt-out upon request;
- Document each member's election to receive plan communications either electronically (alternate format) or other portable media formats;
- Have safeguards in place to ensure that member contact information is current, communication materials are delivered and received timely and appropriately, and important materials are identified in a way that members understand their importance;
- Have a process for automatic mailing of hard copies when electronic versions are undeliverable (for example an expired e-mail account); and
- Have a system in place to monitor and evaluate the effectiveness of the electronic communication process.

Finally, if a plan elects to distribute plan information to members through electronic media (e.g., emails) instead of providing hard copies (paper), the plan is responsible for ensuring that it is in compliance with HIPAA (Health Insurance Portability and Accountability Act of 1996).

40.16 - Standardization of Plan Name Type

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268 (q), 423.2268 (q), Section 1851 (a)(6)

Plan sponsors must include the plan type in each plan's name using standard terminology as developed by the Secretary. This requirement is in effect for plan years beginning on or after January 1, 2010.

Plan sponsors enter and maintain their plan names in the HPMS. The plan name is used by internal CMS systems and in standardized marketing tools, including, but not limited to: the Summary of Benefits (SB), Medicare Options Compare and Medicare Prescription Drug Plan Finder on <http://www.medicare.gov>, and the *Medicare & You* Handbook.

To ensure the consistent use of standardized plan type terminology across all organizations, HPMS will auto-populate the plan type label at the end of each plan name beginning in Contract Year 2010. For instance, an HMO plan named "Golden Medicare Plan" would appear as follows: Golden Medicare Plan (HMO). The auto-generated plan type label will not count toward the fifty (50) character maximum length reserved for the plan name field.

In addition to standardizing the terminology in HPMS, organizations must display the plan type on all marketing materials that include the plan name at the end of the plan name. Plans that have previously incorporated the plan type in their plan names in a position other than at the end of the plan name must now place the plan name at the end on printed marketing materials.

The following exceptions to the plan name requirements apply:

- Plans are not required to include the parentheses with the plan type for materials that are not auto generated from HPMS;
- Operational letters or logos that do not mention the plan name are not required to include the plan type;
- Communication information provided verbally to beneficiaries (e.g., scripts) does not require the plan type designation;
- Plan types that have incorporated the plan type at the end of the plan name (e.g., Gold Plan PFFS) are not required to repeat the plan type in the plan name. This includes auto generated pieces; and
- Model documents do not require inclusion of the plan type throughout the entire document. However plans must include the plan type on the front page of the model document or at the beginning of the model document.

NOTE: SNPs and Employer Group Waiver Plans must include the plan type and plan name on all marketing materials as specified above for all plan types. HPMS will auto populate additional plan types for SNPs and Employer Groups in the future.

The following table outlines the standardized plan type terminology to be generated for each active HPMS plan type.

Table 40.16.1 Standardized Plan Type Terminology

Standardized Plan Type Terminology	
Plan Type	Plan Name with Standardized Plan Type Label
HMO	Plan Name (HMO)
Local PPO	Plan Name (PPO)
HMOPOS	Plan Name (HMOPOS)
ESRD II	Plan Name (HMO-POS)
PSO	Plan Name (PSO)
MSA	Plan Name (MSA)
MSA Demo	Plan Name (MSA)
RFB PFFS	Plan Name (PFFS)
PFFS	Plan Name (PFFS)
1876 Cost	Plan Name (Cost)
1833 Cost	Plan Name (Cost)

PACE	Plan Name (PACE)
PDP	Plan Name (PDP)
Regional PPO	Plan Name (Regional PPO)
Employer PDP	Plan Name (Employer PDP)
Employer PFFS	Plan Name (Employer PFFS)
RFB HMO	Plan Name (HMO)
RFB HMO-POS	Plan Name (HMO-POS)
RFB Local PPO	Plan Name (PPO)
RFB PSO	Plan Name (PSO)
CCRC	Plan Name (HMO-POS)

50 - Marketing Material Types and Applicable Disclaimers

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

In general, CMS groups marketing materials into two distinct categories – General Advertising Materials and Explanatory Marketing Materials. While each category can represent a variety of different material types, the general rules and requirements apply to all materials that fall into a respective category.

Except where noted below, the following disclaimers must be present on all general advertising materials. Please note that if the document is a model document and the CMS model does not include the disclaimers, the disclaimers are not required until that model is updated, unless noted otherwise in CMS guidance.

Plan sponsors are reminded that, in addition to the guidance provided in this section, materials must also comply with the other requirements and responsibilities provided in these guidelines including, but not limited to, section 40 and section 60.

50.1 - Guidance and Disclaimers that Apply to All Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

Except where noted below, the following disclaimers must be present on all general advertising and explanatory marketing materials. A disclaimer must be prominently displayed at the bottom center of the first page of the material and must be of the same font size (refer to §§40.2 and 40.3) and style as the commercial message.

50.1.1 - Federal Contracting Statement

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

All materials must include the statement that the plan sponsor contracts with the Federal government.

Exception: Banner ads, banner-like ads, outdoor advertising, television and Internet banner ads.

At least one of the following statements must be used by MA or MA-PD plans in the contracting statement. The federal contracting statement may be either in the text of the piece or at the end/bottom center of the piece.

- “A/An [insert plan type: HMO, PPO, POS plan, PSO] with a Medicare contract;”
- “An Medicare Advantage organization with a Medicare contract;”
- “A Health plan with a Medicare contract;”
- “A Federally Qualified HMO with a Medicare contract;”
- “A Federally Qualified Medicare contracting HMO;”
- “Medicare approved [insert plan type: HMO, PPO, POS plan, PSO, Cost];” and
- “A Coordinated Care plan with a Medicare Advantage contract.”

The PDP plan sponsors must use one of the following contracting statements below. This information may be either in the text of the piece or as a part of the disclaimer section end/bottom center of the piece.

- “A Federally Qualified Medicare Contracting Prescription Drug Plan;”
- “A Medicare approved Part D sponsor;” and
- “A stand alone prescription drug plan with a Medicare contract.”

50.1.2 - Benefit Changes

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.111(a), 422.111(b), 422.111(f)(1)423.128(b)

Effective October 1 each year, plan sponsors must include a statement in their current contracting year marketing materials when advertising a current year benefit, formulary, pharmacy network, premium, or co-payment that may or will change in the upcoming

contracting year or whenever it accepts an election for a revised effective date of November 1 or December 1 in the current contracting year.

The following model disclaimer may be used by plan sponsors with benefit changes in the upcoming contracting year.

[Insert any or all of the following, whichever is appropriate: Benefits, formulary, pharmacy network, premium and/or co-payments/co-insurance may change on January 1, <XXXX>. Please contact [insert plan sponsor name] for details.]

Additional regional office review and approval is not required if this disclaimer is used verbatim, but is required if it is modified.

EXCEPTION: The benefit changes disclaimer does not need to be included within the text of enrollment forms, but must be provided with enrollment forms provided to prospective members after October 1 each year for elections that may become effective on November 1 or December 1 of the current contracting year.

50.1.3 - Additional Guidance Applicable to All PFFS Plan Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.4(a) (3) (ii), 422.216(a), (b) and (d)

The following PFFS disclaimer must be prominently displayed within all materials including, but not limited to, advertisements, enrollment-related materials, web-based information, materials used at sales presentations by agents and brokers (employed and contracted) of the MAO in public venues, and private meetings with beneficiaries.

“A Medicare Advantage Private Fee-for-Service plan works differently than a Medicare supplement plan. Your doctor or hospital can continue to treat you if it agrees to accept our terms and conditions of payment, and thus may choose not to treat you, with the exception of emergencies. If your doctor or hospital does not agree to accept our payment terms and conditions, they may choose not to provide health care services to you, except in emergencies. Providers can find the plan’s terms and conditions on our website at: [insert link to PFFS terms and conditions].”

EXCEPTIONS: CMS model documents that do not contain the disclaimer in model language.

- Formulary;
- Pharmacy directory; and
- Banner ads, banner-like ads, and outdoor advertising; and

- Marketing materials that mention multiple plan types (e.g., HMO, PPO, and PFFS) without mentioning any specific benefits of the PFFS plan.

All marketing representatives selling PFFS plans are required to verbally review the disclaimer during sales presentations in public venues and private meetings with beneficiaries.

Any statement indicating that enrollees may see any provider must also include, the phrase “*who agrees to accept our terms and conditions and thus may choose not to treat you with the exceptions of emergencies.*”

The PFFS plans are prohibited from using any materials or making any presentations that imply PFFS plans function as Medicare supplement plans or use terms such as “Medicare Supplement replacement”. MAOs may not describe PFFS plans as plans that cover expenses that Original Medicare does not cover nor as plans that offer Medicare supplemental benefits. However, it would be permissible for PFFS plans to clarify that the plan does not pay after Medicare pays its share, but rather, it pays instead of Medicare and the beneficiary pays any applicable cost-share or co-pay.

Model language is provided to incorporate into sales presentations describing the special aspects of PFFS plans which differ from supplements and other MA plans (refer to <http://www.cms.hhs.gov/PrivateFeeForServicePlans/>).

PFFS plans should refer to above web link for additional information on the inclusion of balance billing notification in the EOC.

50.1.4 - Additional Guidance for SNP Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2, 422.4(a)(1)(iv), 422.111(b)(2)(iii)

For the 2010 contract year, plan sponsors offering dual-eligible SNPs must provide each prospective enrollee, prior to enrollment, with a comprehensive written statement of benefits and cost-sharing protections under the SNP as compared to protections under the relevant State Medicaid plan. MIPPA also limits the dual-eligible SNPs from imposing cost-sharing requirements on specified dual-eligible individuals that would exceed the amounts permitted under the State Medicaid plan if the individual were not enrolled in the dual-eligible SNP. This requirement will assist a prospective dual-eligible enrollee in determining if he/she will receive any value from enrolling in the dual-eligible SNP that is not already available under the State Medicaid program.

Plan sponsors that market to all duals must also include a statement that premiums, co-pays, co-insurance, and deductibles may vary based on the level of help that beneficiaries may receive and that the beneficiary should contact the plan for further details.

Plan sponsors must include the eligibility requirements for SNP enrollment on all materials. Some examples a plan sponsor can use are:

- “This plan is available to anyone who has chronic alcohol and other drug dependence;”
- “This plan is available to all people with Medicare who have been diagnosed with HIV/AIDS;” and
- “This plan is available to anyone who has both Medical Assistance from the State and Medicare.”

50.1.5 - Plan Sponsor Responsibility -Disclaimer When Providing Third Party Marketing Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

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

Therefore, if a non-benefit/service-providing third party wishes to market to a plan sponsor’s members, it must submit its materials to the plan sponsor, which in turn, may distribute the materials to its membership. It is the plan sponsor’s responsibility to ensure that these marketing materials contain the disclaimer:

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

This disclaimer must be prominently displayed at the bottom center of the first page of the material and must be of the same font size and style as the commercial message. See §§40.14.6 and 70.9.7 for further detail on third-party marketing materials.

50.1.6 Plan Sponsor Responsibility -Disclaimer for Materials that are Co-branded with Providers

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

422.2268, 423.2268

Plan sponsors that choose to enter into co-branding relationships with network providers are required to include all co-branded provider names and/or logos on marketing materials related to the member’s selection of specific providers or provider organizations (e.g., physicians, hospitals. Refer to §30.2 for additional information on co-branding. Co-branding marketing materials are required to include the following language disclaimer located below:

“Other <Pharmacies/Physicians/Providers> are Available in Our Network”.

50.1.7 Applicable Disclaimers for the Marketing of Educational Events

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

CMS requires that the following disclaimer be used when an educational event is organized, sponsored or promoted by a plan sponsor and should be included on all announcements.

"This event is only for educational purposes and no plan specific benefits or details will be shared."

This disclaimer is not required when a plan sponsor is invited to be a participant in an educational event sponsored, organized or promoted by an entity other than the plan sponsor.

50.2 - Specific Guidance Applicable to General Advertising Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2260, 423.2260

General advertising materials are primarily intended to attract or appeal to a potential enrollee and allow them to request additional information to make an educated decision on their purchase. As such, advertising materials contain less detail than “explanatory marketing materials” as outlined below in §50.4. General advertising materials may provide basic benefit information to entice a potential enrollee to request additional information. Please see §50 for additional requirements when mentioning benefits in general advertisements.

Examples of advertising materials include:

- Banner and Banner-like Ads;
- Counter Tents;
- Direct Mail that does not include enrollment forms, postcards, self-mailers, home delivery coupons, and reply cards. (Refer to §20 for definition);
- Event Signage;
- Internet Advertising;
- Outdoor Advertising (ODA) such as billboards or signs attached to transportation vehicles;
- Pharmacists’ promotional buttons;

- Post Stands and Free Standing Inserts (newspapers, magazines);
- Print Ads (newspaper, magazine, flyers, brochures, posters, church bulletins);
- Radio Ads;
- Window Stickers; and
- Envelopes that contain marketing messaging (excluding logos or other means of branding).

50.2.1 - Radio Advertisements

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

Radio advertisements for a plan sponsor must include the plan sponsor's toll-free number. The Federal contracting statement is not required; however, any other required disclaimers can be worked into the script or they can be read at the end of the spot.

Please note that all radio advertisement scripts must be submitted to CMS as outlined in §80. They do not have to mention the date on which CMS approved the script for the radio. Radio advertisements qualify for File & Use review.

50.2.2 - Television Advertisements

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

Television advertisements placed by plan sponsors must include their toll-free number. This information must be displayed on the crawl or banner. The Federal contracting statement is not required; however, any other required disclaimers (e.g., actor portrayal) must be worked into the script and/or shown on the screen.

Please note that all television advertisement scripts must be submitted to CMS as outlined in section 80. They do not have to mention the date on which CMS approved the script for the television. Television advertisements qualify for File & Use review.

50.3. Applicable Disclaimer When Benefits Are Mentioned

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

General advertising materials may provide basic benefit information to entice a potential enrollee to request additional information, for example including co-pay amounts, monthly premium costs, or a specific coverage type. General advertising materials should not provide benefit information at a level that could cause a beneficiary to believe that the information provided was comprehensive.

To that end, when benefit information is provided as a part of a general advertisement, the following disclaimer must be utilized:

“The benefit information provided herein is a brief summary, but not a comprehensive description of available benefits.. Additional information about benefits is available to assist you in making a decision about your coverage. This is an advertisement; for more information contact the plan”.

50.3.1 Disclaimers on Advertisements and Invitations to Sales/Marketing Events

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

Advertisements and invitations to Sales/Marketing Events (in any form of media) that are used to invite beneficiaries to attend a group session with the possibility of enrolling those individuals attending must include the following two statements:

- “A sales person will be present with information and applications.; and
- “For accommodation of persons with special needs at sales meetings, call <insert phone and TTY numbers>.”

Such invitations must also clearly state all of the products that will be discussed (for example HMO, PDP) during that event.

50.3.2 - Disclaimers Applicable to Advertising that Promotes a Nominal Gift

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268(b), 423.2268(b)

A statement must be made concerning drawings, prizes or any promise of a free gift and must include a disclaimer that there is no obligation to enroll in the plan. For example:

- “Eligible for a free drawing and prizes with no obligation.”
- “Free drawing without obligation.”

For additional information on nominal gifts please reference §70.2.

50.4 - Explanatory Marketing Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

In general, explanatory marketing materials include those materials that are sent to prospective members prior to enrolling (pre-enrollment) and to current and new members as a part of their enrollment (post-enrollment). While all CMS required marketing materials fall under this category, other plan generated materials that include a high level of detail with regard to plan benefits and costs, such as sales brochures, are also included.

50.5 - Guidance and Disclaimers Applicable to Explanatory Marketing Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

Except where noted below, the following disclaimers must be present on all explanatory marketing materials. Please note that for the purpose of disclaimer/language requirements, the enrollment kit, as described in section 30.9.1 of these guidelines, can be treated as one mailing, and all of the required disclaimers must be included at least once within the kit. However, if a plan uses any one piece from the kit as a stand-alone material, it must contain all of the required disclaimers.

Examples of explanatory marketing materials include:

- Summary of Benefits (SB);
- Explanation of Benefits (EOB);
- Combined Annual Notice of Change/Evidence of Coverage;
- Provider Directory;
- Pharmacy Directory;
- Member Handbook;
- Detailed Plan Brochures;
- Plan Websites;
- Formularies; and
- Enrollment Forms.

50.5.1 - Required Access Information Disclaimers

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

One of the following statements is required on all pre-enrollment materials used by all MA and MA-PD plans whose members are locked into a provider network (if the member obtains routine care from an out-of-network provider neither the plan nor Original Medicare will be responsible for the cost of care):

- For materials of short duration: *“You must receive all routine care from plan providers.”*
- In all other written materials: *“You must use plan providers except in emergent or urgent care situations <<or for out-of-area renal dialysis>>. If you obtain routine care from out-of-network providers neither Medicare nor <name of MA plan sponsor> will be responsible for the costs.”*

Plan sponsors with a visitor traveler program for any applicable plan type must explain that the use of out-of-network or non-preferred providers is allowed, but may cost more for the beneficiary.

50.5.2 - Enrollment Limitations

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

For explanatory marketing materials that are provided prior to enrollment, plan sponsors must include a statement indicating that members may enroll in a plan only during specific times of the year. Plan sponsors may either describe all enrollment periods (i.e., the annual election period, special election periods, and the initial election period) in detail or refer eligible individuals to the plan sponsor’s customer service department to obtain more information. The exception to this guidance is for plan sponsors offering SNPs for dual eligibles and/or SNPs for institutionalized individuals for which the statement should indicate that eligible beneficiaries can enroll at any time.

50.5.3 - Explanatory Marketing Materials that Mention Benefit and Plan Premium Information

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.111(a)(2), 423.128(a)(2), 422.2264, 423.2264

Materials for all plan sponsors that describe benefit and plan premium information must:

- Include the statement: *“You must continue to pay your Medicare Part B premium”* with premium information, even if the plan premium is \$0. [NOTE: Full benefit dual SNPs for whose members the State pays the Part B premium should indicate that the Part B premium is covered for full benefit dual members;]

- Clearly state to beneficiaries that if they decide to switch to premium withhold or move from premium withhold to direct bill, it could take up to three months for it take effect and they will ultimately be held responsible for those premiums;
- When specifying benefits (e.g., \$5 co-payment for each doctor visit) plan sponsors should specify applicable annual limits, annual benefit payout, and co-payments;
- Clearly state major exclusions and limitations. It is not acceptable to just have a disclaimer that states that exclusions and limitations exist;
- Clearly state all monetary limits, as well as any restrictive policies that might impact a beneficiary's access to services;
- When annual dollar amounts or limits are provided, also mention the applicable quarterly or monthly limits and whether any unused portion of that benefit can be carried over from one calendar quarter to the next; and
- Include a closing statement such as: *“For full information on <organization name> benefits, call our Customer Service Department at <include phone number(s) and hours of operation>.”*

All plan sponsors should have explanatory marketing materials detailing eligibility requirements, monthly premiums, or other costs for Part D benefits. Plan sponsors must include the following language in paragraph or bullet form:

“You may be able to get Extra Help to pay for your prescription drug premiums and costs. To see if you qualify for getting Extra Help, call:

- *1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048, 24 hours a day/7days a week;*
- *The Social Security Office at 1-800-772-1213 between 7 a.m. and 7 p.m., Monday through Friday. TTY users should call, 1-800-325-0778; or*
- *Your State Medicaid Office.”*
- *In addition, we encourage plans to insert the following on all of their materials that include benefit and premium information: “People with limited incomes may qualify for Extra Help to pay for their prescription drug costs. If eligible, Medicare could pay for seventy-five percent of drug costs including monthly prescription drug premiums, annual deductibles, and co-insurance. Additionally, those who qualify will not be subject to the coverage gap or a late enrollment penalty. Many people are eligible for these savings and don’t even know it. For more information about this Extra Help, contact your local Social Security office or call 1-800-MEDICARE (1-800-633-4227), 24 hours per day, 7 days per week. TTY users should call 1-877-486-2048.”*

Since the Federal subsidy for low-income individuals (“Extra Help”) is not available in the territories, marketing materials for plan sponsors with plans offered in the territories may refer residents directly to their Medical Assistance office.

50.5.4 - Pharmacy Network Limitations

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.120

All plan sponsors offering Part D benefits must include a statement that indicates that eligible beneficiaries must use network pharmacies to access their prescription drug benefit, except under non-routine circumstances when they cannot reasonably use network pharmacies.

In addition, if benefits are mentioned, Part D sponsors must:

- Inform eligible individuals of the types of pharmacies included in their network (e.g., retail, mail order, LTC, I/T/U, and home infusion).; Provide information on ways for members to obtain additional information regarding mail-order prescription drug service, if available.
- Provide information on quantity limitations and requirements for mail-order prescription drug service, if mail order prescription drug service is offered by the plan;
- Indicate that, in general, benefits are only available at the contracted network pharmacies; and
- Provide contact information for obtaining additional network pharmacy information, including a toll-free number (with hours of operation), a TTY number, and a mailing address.

50.5.5 - Online Enrollment Center Disclaimer

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

All plan sponsors must accept enrollment into a plan through the Online Enrollment Center (OEC). The OEC is accessible through Medicare Options Compare (MOC) and Medicare Prescription Drug Finder (MPDPF) on <http://www.medicare.gov>.

With the exception of a few plan sponsors accepting enrollment requests into a plan through the OEC must state the following disclaimer in pre-enrollment materials:

“Medicare beneficiaries may enroll in <Plan Name> through the Centers for Medicare & Medicaid Services Online Enrollment Center, located at <Website>. For more information contact the <Plan Name> at <Plan Phone Number>.”

NOTE: There are few exceptions for certain plan types that are not required to or cannot accept enrollment through the OEC. These plan types include 1876 Cost Plans, Medicare Savings Account (MSA) plans, 800-Series Employer plans, SNPs and Religious Fraternal Benefit plans.

50.5.6 - Eligibility Requirement Disclaimers

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

Plan sponsors must clearly state in their pre-enrollment materials the eligibility requirements to enroll and remain enrolled in the plan.

PDPs must also state that Medicare beneficiaries:

- Enrolled in an MA PFFS plan that includes Medicare prescription drugs or any MA coordinated care (HMO or PPO) plan will be automatically disenrolled from the HMO, PPO or MA PFFS plan if they enroll in a PDP; and
- Enrolled in a private fee-for-service plan (PFFS) that does not include Medicare prescription drug coverage, an MA Medicare Savings Account (MSA) plan or an 1876 Cost plan may enroll in a PDP and will not be automatically disenrolled from the PFFS, MSA or 1876 CostPplan.

50.5.7 - Availability of Medicare Subsidy Information

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

All Plan sponsors materials are to clearly state the availability of Medicare Subsidy Information and specifically refer to the subsidy as “Extra Help”. Plan sponsors are to include in all pre-enrollment marketing materials detailing eligibility requirements, monthly premiums and other member costs for Part D benefits must include the following language in paragraph or bullet form:

“You may be able to get Extra Help to pay for your prescription drug premiums and costs. To see if you qualify for getting Extra Help, call:

- 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048, 24 hours a day/7days a week);
- The Social Security Office at 1-800-772-1213 between 7 a.m. and 7 p.m., Monday through Friday. TTY users should call, 1-800-325-0778; or
- Your State Medicaid Office.”

50.5.8 - Availability of Alternate Formats

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

Plan sponsors must provide a disclosure on all required explanatory marketing materials, except the ID card indicating:

- The document is available in alternate formats or languages; and
- A phone number the beneficiary can call for the information in other formats or languages.

50.5.9 - Additional Guidance for Preferred Provider Organization (PPO) Plans

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

In addition to the applicable requirements and disclaimers provided above, the following must also be used for PPO plan sponsors:

- If a PPO states in marketing materials that prospective enrollees may save money if they join the plan, it must also include a clear notice that with the exception of emergency or urgent care, it will cost more to get care from out-of-network providers and/or that accessing services from in-network providers can cost less than using services of out-of-network providers.
- If a PPO offers benefits for which the co-insurance percentage is the same both in and out-of-network, the PPO must make it clear in all pre- and post-enrollment material that member responsibility will be greater out-of-network when the out-of-network co-insurance is based on the Medicare allowed amount and the contracted amount is lower.
- The PPO must clearly state in marketing materials that the plan sponsors provides reimbursement for all covered benefits regardless of whether they are received in-network, as long as they are medically necessary.

EXCEPTION: The preceding PPO disclaimers are not required on enrollment forms.

50.5.10 - Additional Guidance for PFFS Plans

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

In addition to the applicable requirements and disclaimers provided above (including the PFFS disclaimer outlined in §50.1.3 of these guidelines), the following must also be used for PFFS plan explanatory marketing materials.

The PFFS plan sponsors must provide enrollees with a complete description of plan rules, including detailed information on a provider's choice whether to accept the plan's terms and conditions of payment. CMS has developed a model document that beneficiaries may show their health care providers for this purpose (refer to <http://www.cms.hhs.gov/PrivateFeeforServicePlans/>).

- The model is a 2-sided leaflet, with information for beneficiaries on one side and information for providers on the reverse.

The leaflet must be included in all enrollment kits that prospective enrollees receive and must be available on the PFFS plan sponsor's Internet website for beneficiaries who enroll online. It may be helpful to provide several copies to each beneficiary so that they can give copies to their health care providers. The leaflet must be submitted to CMS using the File and Use Certification process.

- The PFFS plan sponsors may establish voluntary prior notification policies where the plan charges lower cost sharing for a health care service if the enrollee or provider notifies the plan before the service is furnished. PFFS plan sponsors that have prior notification policies must always state in marketing materials the cost sharing that applies in the absence of voluntary prior notification as well as the "reductions" that might be available if voluntary prior notification is made by enrollees or providers. In other words, PFFS plan sponsors must first explain to potential and current enrollees what the cost sharing will be if the enrollee receives covered services without first notifying the plan. PFFS plan sponsors should then explain the cost sharing reductions they offer to enrollees who participate in voluntary prior notification. PFFS plan sponsors may not require the enrollee or provider to prior notify the plan as a condition for covering a service nor impose penalties (such as denying covered benefits, imposing fines, or monetary penalties) for non-participation in voluntary prior notification protocols.

50.5.11 - Additional Guidance for 1876 Cost Plans

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 417.128 (b)(2)

In addition to the applicable requirements and disclaimers provided above, the following guidance is applicable to 1876 Cost Plans.

The 1876 Cost Plans must describe in their marketing materials the premiums and cost sharing for services received through the cost plan, and any optional supplemental benefit packages they offer. They must also indicate that premiums, cost sharing, and optional supplemental benefits

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

All post-enrollment materials must clearly explain that members may use plan and non-plan providers, and also explain the benefit/cost sharing differentials between use of plan and non-plan providers.

50.6 - Plan Sponsor Mailing Statements on Envelopes/Mailing Itself

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2272(b), 423.2272(b)

All plan sponsors that mail information to Medicare beneficiaries (prospective or enrolled) should include one of the three statements on any envelope or the mailing itself (if no envelope is being sent) that they are sending to Medicare beneficiaries regardless of the materials inside of the envelope. One of the three statements on the outside of the envelope or mailing itself should best fit the information being sent to the Medicare beneficiary which are:

1. Advertising pieces – “This is an advertisement;”
2. Plan information – “Important plan information about your enrollment; and
3. Health – “Health or wellness or prevention information.”

60 - Specific Guidance on Required Documents

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

60.1 - Summary of Benefits (SB)

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.111(b)(2), 422.111(f), 423.128(b)(2)

The Summary of Benefits (SB) is the pre-enrollment document to inform prospective as well as existing enrollees of the benefits offered by the plan sponsor. Plan sponsors should provide the SB to current enrolled members upon request. The information within the SB is standardized language to allow beneficiaries to more easily compare the benefits offered by different plan sponsors.

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 plan. This section is standard language that should not be modified except as indicated in the SB instructions.
- **Section (2):** The benefit comparison matrix, which is an output report of the plan sponsor's plan Benefit Package (PBP); and Premium Table for PDPs: PDPs with identical benefits offered in different regions may insert a table indicating the premium in each region. This section is standard language that should not be modified except as indicated in the SB instructions.
- **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.
- **Section (4):** Effective January 1, 2010, Dual Eligible Special Needs Plans (SNPs) must provide each prospective enrollee prior to enrollment with a comprehensive written statement that describes:
 - The benefits that the individual is entitled to under Title XIX – Medicaid;
 - The cost sharing protections that the individual is entitled to under Title XIX; and
 - Additionally, the comprehensive written statement must describe which of those benefits and cost sharing protections are covered under the specific special needs plan for dual individuals.

The SNPs should include the required comprehensive written statement in section 4 of the Summary of Benefits (SB) when submitting it to CMS for review. SNPs, along with the State, are responsible for ensuring the accuracy of Medicaid benefits displayed in the SB. The Regional Office reviewer is not responsible for review of Medicaid benefits. A template is available on HPMS for plans to use. Technical guidance on the Summary of Benefits can be found in Appendix 1.

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

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 Section 2 of the benefit comparison matrix. Since the Plan Benefit Package (PBP) will only print Sections 1 and 2 of the SB for one plan, organizations will have to create a side-by-side comparison matrix for two (or more) plans by manually combining the information into a chart format. Organizations will also need to modify Section 1 of the introduction section to accurately reflect the plans that have been added to Section 2 of the SB. The side-by-side comparisons are eligible for a ten (10) day marketing review if no other non-global changes are made to the standardized SB.

All plan sponsors, except 1876 Cost Plans, are required to use the standardized SB. 1876 Cost Plans that intend to have a plan appear in the Medicare Personal Plan Finder should refer to the Summary of Benefits for 1876 Cost Plans in Appendix 1.

60.2 - Part D ID Card Requirements

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.120(c), 70 FR 4267

All plan sponsors that offer Part D plans must provide a member identification card to each enrollee within ten (10) calendar days of receiving confirmation of the enrollment from CMS. The member identification card must comply with the most recent version of the National Council for Prescription Drug Program's (NCPDP's) "Pharmacy and/or Combination 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.

The MA-PDs may merge their medical and Part D ID card by adding elements that would identify the Part D benefit, or create a separate ID card for the Part D benefit. Either card must comply with the specifications outlined in the most recent version of the NCPDP Pharmacy and/or Combination ID Card Implementation Guide.

In addition to the NCPDP Pharmacy and/or Combination ID Card standard requirements, the front of the Part D ID Card must include the Medicare Prescription Drug Benefit Program Mark (refer to §150 for more information). Plan sponsors must ensure that the identification number on the ID card cannot be the SSN or Healthcare Insurance Claim Number (HICN) of the enrolled member.

NOTE: Refer to §30.2 regarding co-branding requirements related to ID cards.

60.3 - ID Card Information for MA PPOs and PFFS

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

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

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

NOTE: Refer to §30.2 information regarding co-branding requirements related to ID cards and 60.2 for other related requirements.

In order to ensure that a provider has access to a PFFS plan's terms and conditions of payment, CMS also recommends that PFFS plan sponsors include on their member ID cards: (1) the web link to their terms and conditions of payment, and (2) a phone number for providers to call the plan sponsor. If the web link for the terms and conditions of payment is too long to fit on the member ID card, then PFFS plan sponsors are encouraged to appropriately shorten the web link so that it will fit on the member ID card. Inclusion of both of these items on the member ID card is optional.

60.4 - Directories

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.111(b)(3)(i), 422.111(e), 423.128(b)(5), 423.128 (c) (1)(E), 422.2260, 423.2260

All plan sponsors are required to create and make available applicable directories for their members and prospective members. Plan sponsors must send a complete directory to their members at the time of enrollment and at least every three years from the enrollment date or from the last mailing. The following sections detail the requirements for the various types of directories as well as the options for providing those directories to the Medicare beneficiary.

Plan sponsors (including cost contractors) that have an Internet website must also post copies of their Evidence of Coverage, Summary of Benefits and information on the network of contracted providers and pharmacies (names, addresses, phone numbers, and specialty) on that website.

(NOTE: Employer/Union-only Group Waiver Plans (EGWP) can direct members to their employer for information on the EOC and SB.) With respect to those members who choose to receive a hard copy directory as opposed to an electronic copy, plan sponsors have the option of mailing a complete directory to members instead of mailing only change pages to members. These change pages may be sent after sending a complete directory at the time of enrollment or at any time thereafter (note that, as stated earlier, members must receive a complete directory at least every three years from the enrollment date or from the last mailing). In addition, if at any time a member requests a complete directory, the plan sponsor must comply with the request.

If a plan sponsor chooses to send change pages to members, the following will also apply:

- In instances where significant changes to the provider/pharmacy network occur, the plan sponsor must send a special mailing of change pages immediately. In general, the plan sponsor can define "significant changes" when determining whether a special mailing is necessary. However, CMS may also determine if a mailing is needed, and may direct the plan sponsor to conduct such a mailing.

- A new, complete Provider/Pharmacy Directory must be mailed to all members at least every 3 years from the enrollment date or every three years from the last mailing.
- Change pages may consist of the actual page being changed or a list of changes with referenced pages. Change pages must be dated.
- Plan sponsors may choose to disseminate an errata sheet or addendum during the year to update members with respect to changes in providers' or pharmacies' addresses and phone numbers. Plan sponsors are also required to provide information about contracted providers and pharmacies upon request.
- The first time a plan sponsor sends change pages, a cover letter should be included to explain that the plan sponsor will now be sending change pages to members, as opposed to a complete directory. When sending out change pages, the plan sponsor must include a cover letter that explains that the member can receive a complete directory upon request. In addition, the plan sponsor should include information on how to obtain provider/pharmacy network information on the Internet and/or by telephone.

60.4.1 - Pharmacy Directories

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.111(b)(3)(i), 423.128(b)(5), 423.128 (c) (1)(E)

All plan sponsors that offer Part D plans must include information regarding all contracted network pharmacies in their marketing materials provided at the time of enrollment and annually thereafter, as well as upon beneficiary request. Part D sponsors must provide information about the number, mix, and distribution (addresses) of network pharmacies from which enrollees may reasonably be expected to obtain covered Part D drugs. Part D sponsors may have pharmacy directories for each of the geographic areas they serve (e.g., metropolitan areas, surrounding county areas) provided that all directories together cover the entire service area.

The pharmacy directory must contain the following information. (If Part D sponsors use a search engine on their websites in lieu of posting the Pharmacy Directory, the search engine must include all of the information listed above).

General Disclaimers

- If a directory is a subset of a service area, Part D sponsors must include the following disclaimer: *“This directory is for <geographic area>”. Please contact <Plan Name> at <phone number>, <days and hours of operation>, for additional information.”*
- If a plan sponsor lists pharmacies in its network but outside the service area, Part D sponsors must include the following disclaimer: *“We also list pharmacies that are in our network but are outside <geographic area>. Please contact <Plan Name> at <phone number>, <days and hours of operation>, for additional information.”*

- Part D sponsors must provide a disclaimer that states the directory is current as of a particular date, that the pharmacy's listing in the directory does not guarantee the pharmacy is still in the network, and where to obtain complete and current information about network pharmacies in the plan's areas.

Preferred/Non-Preferred Pharmacies

- Part D sponsors with preferred and non-preferred pharmacies must describe the features of these pharmacy types in terms of higher or lower cost-sharing and must describe restrictions imposed on members that use non-preferred pharmacies.
- Part D sponsors must indicate which of their pharmacies offer preferred cost-sharing.

Restricted Access to Pharmacies

- Part D sponsors must indicate when a pharmacy is not available to all members (for example, a community health center pharmacy that is available only to patients of the community health center).

Information about Pharmacies

- 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, long-term care, home infusion/I/T/U).
- In lieu of providing the addresses for all locations, sponsors may provide a toll-free customer service number for chain pharmacies and a TTY number that an enrollee can call to get the locations and phone numbers of the chain pharmacies nearest to their home. If a chain pharmacy does not have a toll-free number, plan sponsors should include a central number for the pharmacy chain. If the chain pharmacy does not have a central number for enrollees to call, then plans must list each plan's chain pharmacy and phone number in the directory. If the chain pharmacy does not have a TTY number, plan sponsors are instructed to list the TRS Relay number 711. Plan sponsors should not list their own customer service number as a pharmacy phone number or TTY number.
- Part D sponsors may indicate which of their network pharmacies support e-prescribing in their pharmacy directories.
- Part D sponsors must indicate which of their retail pharmacies provides an extended day supply of medications.

60.4.2 - Provider Directories

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.111(b)(3)(i), 423.128(b)(5), 422.111(e)

Plan sponsors are required to disclose all of the plan sponsor's contracted providers to each enrollee in clear, accurate, and standardized form prior to the effective date of enrollment or within 10 calendar days of receipt of the enrollment request and at least annually thereafter (with the exception of those plans who utilize "change pages" as outlined in §60.4). MA and MA-PD plan sponsors usually include this information in their Provider Directory. The directory is then given to new members upon enrollment and existing members on an annual basis. Also, Medicare 1876 Cost Plans are required to send a Provider Directory to members at the time of enrollment and annually.

Beginning in CY 2010 plan sponsors may indicate which of their participating physicians or physician practices support e-prescribing.

60.4.3 - PCP and Specialty Directories

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

422.111(b)(3)(i), 422.111(e), 423.128(b)(5), 423.128 (c)(1)(E)

Plan sponsors may print a separate directory for each sub-network and disseminate this information to members in that particular sub-network. This practice is permissible provided that the directory clearly states that the lists of providers for other networks is available and will be provided to members upon request.

Plan sponsors may publish separate PCP and Specialty directories on the condition that both directories are given to enrollees prior to the effective date of enrollment or within 10 calendar days of receipt of the enrollment request and at least annually thereafter. Plan sponsors that use sub-networks of providers must clearly delineate these sub-networks (preferably by listing the providers as a separate sub-network) and describe any restrictions imposed on members that use these sub-networks. This is particularly important since beneficiaries could choose their primary care physician without realizing that this choice restricts them to a specified group of specialists, ancillary providers, and hospitals. Plan sponsors must also clearly describe the process for obtaining services in these networks and sub-networks, including any referral requirements, as well as any out-of-network coverage or point-of-service option.

60.4.4 - Combined Provider/Pharmacy Directory

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.111(b)(3)(i), 423.128(b)(5)

The MA-PD plans only may combine the model physician and model pharmacy directories in one document. If the plan sponsor chooses to use the two model directories and combine them into one document without modification, it may be submitted for File & Use and for a 10 day review period. If the plan sponsor chooses to use the model directories (provider or pharmacy) separately without modification then they may be submitted under File & Use.

60.4.5 - Mailing the Provider/Pharmacy Directory to Addresses with Multiple Members

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42CFR 422.111(b)(3)(i), 423.128(b)(5)

With respect to the mailing of the directory at the time of enrollment and annual thereafter, plan sponsors have the option to either mail one directory to every member, or to mail one directory to every address where up to four members reside. (Individuals in, for example, apartment buildings, are only considered to be at the “same address” if the apartment number is the same.) Please note that every member must still receive his or her own directory at the time of enrollment.

If a plan sponsor chooses to mail the directory to every address where up to four members reside, the following requirements apply:

- If a member at that address subsequently requests that the plan sponsor mail another copy of the directory, the plan sponsor must mail him/her a directory; and
- When mailing a directory to one address, the plan sponsor must include the name of at least one of those individuals in the mailing address. However, the plan sponsor should include the names of all individuals to prevent confusion;

60.4.6 - Changes to Provider Network

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.111(e)

All MA and MA-PD plan sponsors must make a good faith effort to provide written notice of termination of a contracted provider at least 30 calendar days before the termination effective date to all members who are patients seen on a regular basis by the provider whose contract is terminating, irrespective of whether the termination was for cause or without cause. When a contract termination involves a primary care professional, all members who are patients of that primary care professional must be notified.

60.5 - Formulary and Formulary Change Notice Requirements

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.120(b)(5) 423.128 (a)-(e)

Section 42 CFR 423.128 requires that Part D sponsors provide a list of drugs included on their Part D formulary to enrollees at the time of enrollment and at least annually thereafter. Because our regulations do not specify whether this list should be an abridged or comprehensive list of

covered drugs, and given concerns that a comprehensive formulary would be costly for plan sponsors to print and distribute and confusing for enrollees to use, CMS allows plan sponsors to provide an abridged version of their formulary provided certain requirements, described below, are met.

Part D sponsors are responsible for ensuring that their marketed formularies (both those in print and those available on their websites) are consistent with their HPMS approved formulary file. In addition to each covered drug displaying at the correct cost-sharing tier and with the approved utilization management edits, the formulary drug category and class must also be consistent between the HPMS approved formulary file and the print and web-based marketing versions. Part D plan sponsors must include the applicable HPMS approved formulary file submission ID and version number on their marketed (print and web-based) formularies. This HPMS approved formulary file number refers to the HPMS formulary submission ID number of the approved formulary that is being marketed. The formulary submission version is also required. In the event that a discrepancy is identified, the plan sponsor must continue to cover the drug(s) at the more favorable cost share or with less restrictive utilization management for the beneficiary through the end of the contract year.

Any drug adjudicated as a formulary drug at the point of sale must be included in Part D sponsor marketing materials. This applies to drugs that exist on the approved HPMS formulary as well as drugs covered as Part D formulary enhancements to the approved formulary. Generally these drugs are expected to relate to newly approved brand or generic drugs (including new formulations and strengths) that do not currently reside on the Formulary Reference File (FRF), but that would likely be added during subsequent FRF updates. These marketed formulary drug enhancements must be added to the HPMS formulary once the drugs are represented on the FRF.

60.5.1 - Abridged Formulary

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.128

At a minimum, a Part D sponsor's printed abridged formulary document must include the following information:

- Plan Name on the cover page;
- "<Year> Formulary (List of Covered Drugs)" on the cover page;
- "PLEASE READ: THIS DOCUMENT CONTAINS INFORMATION ABOUT THE DRUGS WE COVER IN THIS PLAN" on the cover page;
- The following statement: "Note to existing members: This formulary has changed since last year. Please review this document to make sure that it still contains the drugs you take;"

- The following disclaimer: “This document includes <Plan’s Name> partial formulary as of <formulary date>. For a complete, updated formulary, please visit our <website address> or call <toll free number>, <days and hours of operation>. TTY users should call <toll free TTY number>;
- The definition of a formulary as compared to an abridged formulary (42 CFR 423.4 defines “formulary” as “the entire list of Part D drugs covered by a Part D plan”);
- An explanation of how to use the Part D plan’s formulary document;
- The following statement: “<Part D Plan Name> covers both brand name drugs and generic drugs. A generic drug is approved by the FDA as having the same active ingredient as the brand name drug. Generally, generic drugs cost less than brand name drugs;
- A statement describing the Part D plan’s general utilization management procedures, as well as a statement that the formulary may change during the year (**NOTE:** As provided under 42 CFR 423.120(b)(6), a Part D plan may not make negative formulary changes to 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;
- An explanation of how to obtain an exception to the Part D plan’s formulary, utilization management tools or tiered cost sharing and a description of the plan’s drug transition policy;
- Plan contact information for additional information or questions on the formulary;
- 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. The category or class names must be the same as those found on the CMS approved Part D plan formulary. (**NOTE:** While Part D plans must ensure that at least two drugs per therapeutic class are included within the abridged formulary, Part D plans have the option to include the therapeutic classes as subheadings within the abridged formulary, as this level of detail may be confusing for beneficiaries.) The row of the chart must include at least the three items described below;
 - **Drug Name:** We suggest capitalizing brand name drugs (e.g., LIPITOR) and listing generic drugs in lowercase italics (e.g., penicillin). Part D plans may include the generic name of a drug next to the brand name of the drug. The abridged formulary may only consist of drugs included on the CMS

approved HPMS formulary. Formulary drug enhancements described in §60.5 may not be included in the abridged formulary document;

- 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 and the corresponding tier label description (e.g., Generic or Preferred Brand) from the approved PBP. Part D plans may also choose to include a column providing the co-payment or co-insurance amount for each tier;
- Utilization Management: Part D plans must indicate any applicable utilization management tools (e.g., prior authorization, step therapy, and quantity limit restrictions) for the drug. A description of the indicator used to describe the utilization management tools must be provided somewhere within the document (e.g., in footnotes). For example, a Part D plan may choose to designate a prior authorization on a drug by placing an asterisk next to the name of the drug.
- Because many beneficiaries may only know the name of their prescription and not its therapeutic class, the abridged formulary must also include an index listing drugs in alphabetical order that directs the reader to the page containing complete information for that drug (e.g., name, tier placement, and utilization management strategy); and
- Plan sponsors must explain any symbols or abbreviations used to indicate utilization management restrictions, drugs that are available via mail-order, excluded drugs, free first fill drugs, limited access drugs, drugs covered in the coverage gap, and drugs covered under the medical benefit (for home infusion drugs only).

60.5.2 - Comprehensive Formulary

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.4, 423.128(c)(1)(v)

As provided in 42 CFR 423.128(c) (1) (v), a Part D plan upon the request of a Part D eligible individual, must provide “the Part D plan’s formulary.” 42 CFR 423.4 defines “formulary” as “the entire list of Part D drugs covered by a Part D plan.” These provisions together require a Part D plan sponsor 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. That is, a 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. Customer service representatives also may inform individuals that current and comprehensive formulary information is available on the Part D plan's website. Nevertheless, the Part D plan still must provide the requested comprehensive written formulary unless the individual indicates otherwise.

The comprehensive formulary must include the same information provided within the abridged formulary document, except that the comprehensive formulary must include the entire list of drugs covered by the Part D plan and excludes the disclaimer informing beneficiaries that they can obtain a comprehensive formulary by contacting the Part D plan. Any drugs adjudicated at the point of sale as formulary drugs must be included in the comprehensive formulary. This may include drugs that are not found on the CMS approved HPMS formulary as described in §60.5.

60.5.3 - Changes to Printed Formularies

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.128(a)-(c)

Beneficiaries have a legitimate expectation that they will have access to the Part D drugs included in marketed formularies. While Part D sponsors can readily update their online formularies, the same is not true for printed formularies provided to plan enrollees.

Given the “bait and switch” nature of mid-year non-maintenance formulary changes (defined in §30.3.3.3 of Chapter 6 of the Prescription Drug Benefit Manual), beginning in contract year 2010, Part D sponsors will be expected to update all impacted abridged and comprehensive printed formularies with any CMS approved non-maintenance formulary changes.

Part D sponsors may make any necessary changes via errata sheets mailed to beneficiaries; however, Part D sponsors retain the flexibility to utilize other processes for notifying beneficiaries of non-maintenance changes to their printed formularies. We clarify that this new requirement does not extend to mid-year maintenance changes defined in §30.3.3.2 of Chapter 6 of the Prescription Drug Benefit Manual. Changes to previously printed formularies resulting from mid-year maintenance changes may be made at the time of the next printing. This is not a substitute for the required advance 60 days notice to affected beneficiaries.

60.5.4 - Formularies Provided on Plan Websites

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.128(d)(2)(ii)

In addition to the preceding print formulary requirements, plan sponsors must include their current formulary and any applicable quantity limit restrictions, prior authorization criteria and step therapy criteria on their website. To meet this requirement Part D plan sponsors must provide an electronic copy of the comprehensive formulary, prior authorization and step therapy

documents that individuals may view and/or print. The formulary should include the tier level and tier label description as well as the quantity limit amount and quantity limit days supply. The utilization management documents must include all prior authorization and step therapy criteria applied to each formulary drug. While Part D sponsors may make minor modifications on plan websites with regard to the HPMS prior authorization and step therapy criteria to address issues such as abbreviations and/or grammatical truncation, Part D sponsors will be expected to display all of the information contained within the HPMS files. For drugs with a Part B versus D administrative prior authorization requirement, the following statement must be included: *“This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.”* The information in the comprehensive formulary and utilization management documents must:

- Be available at the start of each new contract year enrollment period;
- Be updated at least once per month and must be accessible by a drug name search;
- Include the date when the formulary and utilization management documents were last updated; and
- Be posted as PDF files that allow for printing, content copying for accessibility, page extraction, and document assembly. In addition to the PDFs, Part D plans may also post the comprehensive formulary in other downloadable formats.

CMS suggests that Part D plan sponsors also provide a search tool that allows individuals to search for their specific prescription drug. The search tool may not be used as a substitute for the downloadable comprehensive formulary, prior authorization and step therapy criteria documents (PDFs). However, if a search tool is made available, it must be available for all formulary drugs. In addition, CMS also expects the search tool to include the following elements:

- Definition of formulary. Part D plan 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: *“<Part D Plan Name> covers both brand name drugs and generic drugs. Generic drugs have the same active-ingredient formula as a brand name drug. Generic drugs usually cost less than brand name drugs and are rated by the Food and Drug Administration (FDA) to be as safe and effective as brand name drugs.”*;
- A statement that the formulary may change during the year;
- Search results that indicate whether a drug is covered, its tier placement (including the tier number and tier label description), and any applicable utilization management requirements. If quantity limit restrictions apply, the quantity limit amount and days’ supply must be displayed. If prior authorization or step therapy restrictions are applicable, then the criteria must also be included. For drugs with a Part B versus D

administrative prior authorization requirement, the following statement must be included: **“This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.”**;

- An explanation of how to obtain an exception to the Part D plan’s formulary, utilization management tools or tiered cost sharing. This information or a link to this information must be included in both an introductory screen and when search results indicate a drug is not covered;
- An indicator to identify mail-order availability, excluded drugs, free first fill drugs, limited access drugs, drugs covered in the coverage gap, and drugs covered under the medical benefit (for home infusion drugs only); and
- Include the date when the search tool information was last updated.

In addition to the information above, a plan may also choose to include search results that list formulary alternatives for the drug entered in the online search tool. The Part D plan may choose to include non-formulary alternatives in addition to the formulary alternatives; however, the formulary alternatives must be clearly marked as formulary drugs without the need for further navigation. If not all formulary alternatives will be listed, the plan must include the following disclaimer: **“This is not a complete list of all formulary alternatives covered by the Part D plan for the drug you have selected.”**

Formulary information available on a website is subject to review by CMS. Review of these materials will follow the procedures for review of websites, which is described in §100.

60.5.5 - Other Formulary Documents

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.128(b)(4)

Part D plans may develop additional formulary documents provided that the comprehensive and abridged formulary documents are developed and distributed in compliance with section 60.5. For example, Part D plans may choose to develop a formulary that lists all of their preferred drugs or is tailored to individuals with specific chronic conditions, as long as these items supplement the two required documents rather than replace them.

The following disclaimer must also be displayed prominently on the cover of the document: **“This is not a complete list of drugs covered by the Part D plan. For a complete listing, please call <Customer Service Phone Number> or log onto <website address>.”**

60.5.6 - Provision of Notice to Beneficiaries Regarding Formulary Changes

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.120(b)(5)

Part D plans must provide at least 60 days notice to beneficiaries before removing a Part D drug from the Part D plan's formulary; adding prior authorization, quantity limits, step therapy or other restrictions on a drug; or moving a drug to a higher cost-sharing tier. Part D plans can determine the most effective means by which to communicate formulary change information to these parties, including electronic means. Part D sponsors should refer to §30.3.4 of Chapter 6 of the Medicare Prescription Drug Benefit Manual regarding the notice requirements.

60.5.7 - Provision of Notice to Other Payers Regarding Formulary Changes

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.120(b)(5)

Prior to removing a covered Part D drug from its formulary, or making any change in the preferred or tiered cost-sharing status of a covered Part D drug, a Part D sponsor must provide at least 60 days notice to CMS, State Pharmaceutical Assistance Programs, entities providing other prescription drug coverage, authorized prescribers, network pharmacies and pharmacists prior to the date such change becomes effective. Part D sponsors should refer to §30.3.4.2 of Chapter 6 of the Medicare Prescription Drug Benefit Manual for additional information on this notice requirement.

60.6 - Explanation of Benefits

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.128(e)

Part D plan sponsors must send an Explanation of Benefits (EOB) to plan enrollees during months in which enrollees utilize their prescription drug benefits. Part D sponsors must ensure that enrollees who utilize their prescription drug benefits in a given month receive their EOB by the end of the month following the month in which they utilized their prescription drug benefits.

The EOB must include the following information:

- The drugs for which payment was made and the total amount of payment for those drugs, including TrOOP-eligible amounts;
- A notice of the enrollee's right to request an itemized statement;
- A notice of the enrollee's appeal and grievance rights, including the exceptions process;
- Include the cumulative, year-to-date total amounts of benefits (total drug spend) provided relative to:

- The deductible, if applicable;
- The initial coverage limit for the current year, if applicable; and
- The annual out-of-pocket-threshold;
- This cumulative total must include adjustments made as a result of retroactive adjustments (for example, those based on information received from other plans, reversed claims, and supplemental payer adjustments);
- The cumulative, year-to-date total of TrOOP costs. This cumulative total must include adjustments made as a result of adjustments made (for example, those based on information received from other plans, reversed claims, and supplemental payer adjustments); and
- Notice regarding formulary changes to affected enrollees, as provided in 42 CFR 423.120(b)(5) and in §60.5.

NOTE: Plan sponsors are encouraged to include language promoting the LIS program on the EOB.

60.7 - Annual Notice Of Change (ANOC) and Evidence of Coverage (EOC)

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.111(a)(3), 422.111(d)(2), 423.128 (a)(3)

Plan sponsors are reminded that enrollees must receive the ANOC and EOC no later than October 31 with the exception of fully integrated Dual Eligible SNPs and employer/union group plans. Dual Eligible SNPs may separate the ANOC from the EOC, but must send the ANOC to existing members by October 31st and send the EOC to enrollees by December 31st.

Employer/union group plans ANOCs and EOCs are required to be received by the beneficiaries no later than 15 days before the beginning of the Annual Coordinated Election Period (ACEP) which is based on the employer/union sponsor's open enrollment period (refer to Chapter 12 of the Medicare Managed Care Manual). Plan sponsors must also send the ANOC/EOC notice to all new members who enroll in a plan with an effective date of November 1st or December 1st. For enrollments with an effective date of January 1st, plan sponsors may separate the documents and send a standalone EOC that may be edited to remove all references to the ANOC. Plan sponsors doing so do not need to resubmit the standalone EOC under a new code for CMS approval. In either case, the document must be provided to all new enrollees no later than ten (10) calendar days of the receipt of CMS confirmation of enrollment, or by the last day of the first enrollment month, whichever occurs first. During the same time these members (members that enroll in November 1 and December 1) must also receive the ANOC/EOC for the upcoming plan year.

All 1876 Cost Plans do not need to use the standardized combined ANOC/EOC but they must provide information to beneficiaries. In addition, the date by which cost plan enrollees must

receive the ANOC/EOC in the beneficiaries' hands is different, and 1876 Cost plans should follow the guidance provided in yearly call letter for those dates.

To ensure that plan sponsors are mailing their ANOC/EOC timely, plan sponsors must indicate the actual mail date in HPMS after the material has been approved. Plan sponsors should enter the actual mail date within 3 days of mailing. Plan sponsors that mail in waves should enter the actual date of the last wave.

70 - Promotional Activities, Events, and Outreach

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

70.1 - General Guidance about Promotional Activities

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

Promotional activities (including provider promotional activities) must comply with all relevant Federal and State laws, including when applicable the anti-kickback statute and the civil monetary penalty prohibiting inducements to beneficiaries. A plan sponsor may be subject to sanctions if it offers or gives something of value to a Medicare beneficiary that the plan sponsor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare. Marketing representatives must clearly identify the types of products that will be discussed before marketing to a potential enrollee. This includes all sales presentations, events, appointments, and outbound calls that are permissible under CMS' unsolicited contacts guidance. Additionally, plan sponsors are prohibited from offering rebates or other cash inducements of any sort to beneficiaries.

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

Promotional items may only be offered to promote one of the following activities:

- “Welcome to Medicare” visit (includes a referral for an ultrasound screening for abdominal aortic aneurysm for eligible beneficiaries);
- Adult Immunization – influenza, pneumococcal and Hepatitis B vaccination;
- Colorectal Cancer Screening;
- Screening Mammography;
- Screening Pap Test and Pelvic Examination;

- Prostate Cancer Screening;
- Cardiovascular Disease Screening;
- Diabetes Screening;
- Glaucoma Screening;
- Bone Mass Measurement;
- Diabetes Self-Management, Supplies and Services;
- Medical Nutrition Therapy; and
- Smoking Cessation.

Any promotional activities or items offered by plan sponsors, including those that will be used to encourage retention of members, and to promote one of the above activities:

- Must be of nominal value;
- Must be offered to all eligible members without discrimination; and
- Must not be offered in the form of cash or other monetary rebates.
- May not be an items that are considered a health benefit (e.g., a free checkup);
- May not consist of lowering or waiving co-pays;
- May not be items that are otherwise available, to the general public, for free.
- May not be used in pre-enrollment advertising, marketing, or promotion of the plan, such as in the PBP, SB, ANOC or EOC (rewards and incentives may only be discussed in post-enrollment notifications);
- May not be structured to steer enrollees to particular providers, practitioners, or suppliers;
- May be discussed in direct mailings to enrollees (as long as there is no violation of the Health Insurance Portability and Accountability Act (HIPAA) privacy laws);
- Must be tracked and documented during the contract year;
- Are subject to grievances by the enrollee (consequently, the plan must explicitly advise enrollees of the right to grieve and the process for filing a grievance);
- May not be tied directly or indirectly to the provision of any other covered item or service; and

- Must comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil monetary penalty prohibiting inducements to beneficiaries.

70.2 - Nominal Gifts

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268(b), 423.2268(b)

Pursuant to 42 CFR §422.2268(b) and 42 CFR §423.2268(b), plan sponsors can offer gifts to potential enrollees at all marketing activities as long as such gifts are of nominal value and are provided whether or not the individual enrolls in the plan. Nominal value is currently defined as an item worth \$15 or less, based on the retail purchase price of the item. The following rules must be followed when providing gifts of a nominal value:

- If more than one item is offered by a plan sponsor at any marketing activities (for example a pen and a flashlight), the combined value of all items offered to a participant must not exceed \$15;
- If a nominal gift provided is one large gift that is enjoyed by all in attendance (for example a concert or a magician) the total retail cost must be \$15 or less when it is divided by the estimated attendance. For planning purposes, anticipated attendance may be used, but must be based on venue size, response rate, or advertisement circulation;
- Local Medicare fee-for-service fiscal intermediary and/or carrier charge listings can be used to determine the value of medical services, examinations, and laboratory tests, associated with nominal value determinations in marketing scenarios; and
- Cash gifts are prohibited, including charitable contributions made on behalf of potential enrollees and including gift certificates and gift cards that can be readily converted to cash, regardless of dollar amount.

NOTE: Gift cards must be used in their entirety and the balance cannot be issued in cash. Plan sponsors should refer to the Office of Inspector General's website regarding advisory opinions on gift cards at <http://www.oig.hhs.gov/fraud/advisoryopinions.asp>.

The dollar amount associated with the definition will be periodically reassessed by CMS. A plan sponsor may offer a prize of over \$15 to the general public (for example, a \$1,000 sweepstakes on its corporate website) as long as the prize is offered to the general public and not just to Medicare beneficiaries, is not routinely or frequently awarded and is awarded without regard to whether the individual enrolls in a plan.

70.2.1 - Exclusion of Meals as a Nominal Gift

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268(p), 423.2268(p)

As outlined in 42 CFR 422.2268(p) and 42 CFR 423.2268(p), plan sponsors may not provide prospective enrollees with meals, or have meals subsidized, at any event or meeting at which plan benefits are being discussed and/or plan materials are being distributed (for example a soup kitchen, shelter, or senior center).

Plan sponsors are, however, allowed to provide refreshments and light snacks to prospective enrollees. Plan sponsors must use their best judgment on the appropriateness of food products provided, and must ensure that items provided could not be reasonably considered a meal, and/or that multiple items are not being “bundled” and provided as if a meal.

Meals may be provided at educational events provided they meet CMS’ strict definition of an educational event, and comply with the nominal gift requirement in §70.2 Meals are not allowed at sales/marketing events. Please reference §70.7 for Educational events.

While CMS does not intend to define the term “meal” or create a comprehensive list of food products that qualify as light snacks, items similar to the following could generally be considered acceptable:

- Fruit;
- Raw vegetables;
- Pastries;
- Cookies or other small dessert items;
- Crackers;
- Muffins;
- Cheese;
- Chips;
- Yogurt; and
- Nuts.

It is the responsibility of plan sponsors to monitor the actions of all agents selling their plan(s) and take proactive steps to enforce this prohibition. Oversight activities conducted by CMS will verify that plan sponsors and agents are complying with this provision, and enforcement actions will be taken as necessary.

70.2.2 - Nominal Gift Disclaimer

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

Any statement made concerning drawings, prizes or any promise of a free gift must include a disclaimer that there is no obligation to enroll in the plan. For example:

- “Eligible for a free drawing and prizes with no obligation”; and
- “Free drawing without obligation.”

70.3 - Unsolicited E-mail Policy

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268(d) 423.2268(d)

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

- Plan sponsors are prohibited from renting and purchasing e-mail lists to distribute information about Medicare Advantage Plans or the Part D benefit.
- Plan sponsors may not acquire e-mail addresses through any type of directory.

NOTE: Since the plan sponsor is contracted to conduct business on behalf of the Medicare beneficiary, permission to send e-mails to the beneficiary must be received by the plan sponsor and not by an unaffiliated third-party. Only then may the plan sponsor e-mail that beneficiary.

70.4 - Marketing through Unsolicited Contacts

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268(d), 423.2268(d)

As reflected in 42 CFR 422.2268(d) and 42 CFR 423.2268(d), there is a general prohibition on marketing through unsolicited contacts. In general this prohibition includes the following and may extend to other instances of unsolicited contact that may occur outside of advertised sales or educational events. Some examples include:

- Door to door solicitation;
- Approaching beneficiaries in common areas (i.e., parking lots, hallways, lobbies, etc.); and
- Unsolicited telephone or email contact (as noted in §70.3, an email is not considered unsolicited if the beneficiary provides his or her email address).

The prohibition on marketing through unsolicited contacts does not extend to mail and other print media provided they are constructed and approved in accordance with the information set

forth in these guidelines. Leads may still be generated through mailings, websites, advertising and public sales events. Refer to §70.3 regarding email policy.

CMS reminds plan sponsors that they will be held accountable for all actions of agents/brokers selling their products, and plans/agents/brokers should be wary of any company selling beneficiary contacts that claims to be permissible under our guidance. Plan sponsors should also note that CMS marketing guidelines and regulations apply to Medicare age-ins as well as existing beneficiaries.

In addition, permission given by a beneficiary to be called or otherwise contacted is to be considered short-term, event-specific, and may not be treated as open-ended permission for future contacts. All business reply cards used for documenting beneficiary agreement for a contact must be submitted to CMS for review/approval.

70.5 - Specific Guidance on Telephonic Contact

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268(d), 423.2268(d)

Because telephonic contact with Medicare beneficiaries is performed for a variety of reasons, the following guidance has been developed to further clarify the scope of the restrictions. While CMS understands that plan sponsors might have previously received beneficiary consent to contact them for sales activities, we view that previous consent as limited in scope, and short-term, event-specific consent may not be treated as open-ended permission for future contacts. The exceptions are for agents contacting their own clients and also plans/agents contacting their current members.

Prohibited telephonic activities include, but are not limited to, the following:

- Conducting or allowing unsolicited contacts, including unsolicited outbound calls, to beneficiaries to offer a non-MA or non-PDP product if the unsolicited contact also discusses MA or PDP products. (Examples of non-MA or non-PDP products include, but are not limited to: a discount prescription drug card, a Medicare Supplement plan, a needs assessment, an educational event, a review of Medicare coverage options, or any other service or product that is not an MA plan or PDP.);
- Referrals of beneficiaries and/or their contact information resulting in an unsolicited contact. The purpose of this policy is to avoid unsolicited contacts based on a claim by an agent/broker that they have a “referral” from a friend or other third-party. Plan sponsors or agents/brokers are permitted to leave contact information such as business cards with beneficiaries for them to give to friends that they are referring to the agent or plan sponsor. However, in all cases, a referred beneficiary needs to contact the plan or agent/broker directly. A call from an agent to a beneficiary who was referred would be considered an unsolicited contact;

- Outbound marketing calls, unless the beneficiary requested the call. This includes contacting existing members to market other Medicare products, except as permitted below;
- Calls to former members who have disenrolled, or to current members who are in the process of voluntarily disenrolling, to market plans or products, except as permitted below. Members who are voluntarily disenrolling from a plan should not be contacted for sales purposes or be asked to consent in any format to further sales contacts;
- Calls or visits to beneficiaries who attended a sales event, unless the beneficiary gave express permission at the event for a follow-up call or visit (including a completed scope of appointment form); and
- Calls to beneficiaries to confirm receipt of mailed information, except as permitted below.

Plan sponsors may do the following:

- Contact beneficiaries who submit enrollment applications to conduct quality control and agent/broker oversight activities. Scripts for this purpose, like all other call scripts, must be submitted to CMS for review and approval;
- Contact their members or use third parties to contact their current members. Examples of allowed contacts include, but are not limited to, calls to members aging-in to Medicare from commercial products offered by the same sponsoring organization and calls to an organization's existing Medicaid plan members to talk about its Medicare products;
- Conduct outbound calls to existing members to conduct normal business related to enrollment in the plan, including calls to members who have been involuntarily disenrolled to resolve eligibility issues;
- Call former members after the disenrollment effective date to conduct disenrollment surveys for quality improvement purposes. Disenrollment surveys may be done by phone or sent by mail, but neither calls nor mailings may include sales or marketing information;
- Under limited circumstances and subject to advance approval from the appropriate CMS Regional Office, call LIS-eligible members that a plan is prospectively losing due to reassignment to encourage them to remain enrolled in their current plan;
- Call beneficiaries who have expressly given permission for a plan or sales agent to contact them, for example by filling out a business reply card or asking a Customer Service Representative (CSR) to have an agent contact them. This permission applies only to the entity from whom the beneficiary requested contact, for the duration of that transaction, or as indicated by the beneficiary; and
- Return beneficiary phone calls or messages as these are not unsolicited.

Agents/Brokers:

- May contact members that they enrolled in a plan to discuss plan issues and market other plan options, but cannot conduct unsolicited phone calls to other beneficiaries or plan members. During an agent's outbound call to a current member, the agent is not required to set up an appointment to discuss other available plans/products with the beneficiary; and
- May initiate a phone call to confirm an appointment that has already been agreed to by a beneficiary via a completed scope of appointment form.

Plan sponsors may not accept an MA plan or PDP appointment that resulted from an unsolicited contact with a beneficiary (including if the call started based on a non-MA or non-PDP product). We reiterate that any agent/broker who is a producer for an MA or PDP contractor is subject to the CMS marketing requirements at any point that an MA or PDP product becomes part of a discussion with a beneficiary, even if during a sale of an unrelated product, such as long-term care insurance. (See scope of appointment guidance in §70.10.1.)

The exception to this guidance is for Medigap (Medicare Supplement Insurance) outbound telephone calls. Due to the nature and relationship of Medigap and MA/PDP product options, if during the course of an outbound call for a Medigap policy the beneficiary initiates interest in an MA or PDP product, then that MA or PDP product may be discussed, as long as the call is recorded, including the beneficiary-initiated request for MA or PDP product information.

Furthermore, third-parties may not make unsolicited MA or PDP marketing calls to beneficiaries (other than to current plan members if contracted by a plan, as described below) to set up appointments with potential enrollees.

- Third-parties may not make unsolicited calls to beneficiaries for non-MA and PDP products (for example, a "benefits compare" meeting) and provide those contacts to plans for ultimate use as an MA or PDP sales appointment; and
- Sales of MA and PDP products are subject to CMS' scope of appointment guidance, even if conducted during a sales appointment for a Medigap policy.

Finally, for those outbound calls (refer to §70.1, 70.6, and 80.3) that are allowable under these guidelines, plan sponsors must comply to the extent applicable within the following:

- Federal Trade Commission's Requirements for Sellers and Telemarketers;
- Federal Communications Commission rules and applicable State law;
- National-Do-Not-Call Registry;
- Honor "Do not call again" requests, and
- Abide by Federal and State calling hours.

CMS reminds plan sponsors that all outbound scripts utilized by the plan or its contractors must be submitted for review and approval prior to being used in the marketplace. When conducting outbound calls:

- 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.
- Plan sponsors are prohibited from requesting beneficiary identification numbers (e.g., Social Security Numbers, bank account numbers, credit card numbers, Health Insurance Claim Number (HICN), birthdates).
- Plan sponsors are allowed to say they are contracted with Medicare to provide prescription drug benefits or that they are a Medicare-approved MA-PD plan/PDP.
- Plan sponsors cannot use language in outbound scripts that imply that they are endorsed by Medicare, calling on behalf of Medicare, or that Medicare asked them to call the member.

70.5.1 - Specific Guidance on Third-party Contact

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268(d), 423.2268(d)

Sections 42 CFR 422.2268(d) and 42 CFR 423.2268(d) prohibit plan sponsors and their representatives from engaging in direct unsolicited contact with potential enrollees, including outbound calls. This guidance applies to all downstream contractors, including third-party organizations utilized to generate sales leads and/or appointments. As such, plan sponsors should keep in mind that CMS views the following activities as out of compliance:

- Unsolicited MA plan or PDP marketing calls to beneficiaries (other than to current plan members if contracted by a plan, as previously described) to set up appointments with potential enrollees;
- Unsolicited calls to beneficiaries for non-MA and PDP products (for example, a “benefits compare” meeting) and providing those contacts to plans for ultimate use in an MA or PDP sales appointment; and
- Sales of MA and PDP products are subject to our scope of appointment guidance, even if conducted during a sales appointment for a Medigap policy. This includes the requirement for a beneficiary-completed agreement form prior to the appointment and a 48-hour waiting period.

Any plan sponsor or its representative that accepts an appointment to sell an MA or PDP product that resulted from an unsolicited contact with a beneficiary, regardless of who made the contact, will be in violation of the prohibition against unsolicited contacts.

70.6 - Outbound Education and Verification Calls to All New Enrollees

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2272

All plan sponsors are required to conduct outbound education and verification calls to ensure beneficiaries requesting enrollment understand the plan rules. It is important for the plan sponsor's sales staff to obtain from the beneficiary the verification phone number and provide a description of the enrollment verification process to the beneficiary during the application process. The plan sponsor's approved enrollment application form must accommodate this requirement.

Outbound calls mean that calls are made to the beneficiary after the sale has occurred. Calls cannot be made at the point of sale. The plan sponsor must ensure that the verification calls made to beneficiaries who request enrollment through sales agents are not made directly by those sales agents and also that the sales agents are not with the beneficiaries at the time of the verification call. The plan sponsor will be required to conduct these calls for all new enrollments except enrollments into employer or union sponsored PFFS plans or switches from one plan to another plan offered by the same MA organization. A model script has been developed for use by all plan sponsors for this purpose (refer to <http://www.cms.hhs.gov/PrivateFeeforServicePlans/>).

The plan sponsor may continue to use existing scripts provided the information in the model script is conveyed during verification calls. The plan sponsor's script must be submitted to CMS through the normal process for approval.

Three documented attempts to contact the applicant by telephone within 10 calendar days of receiving the application are required. If the plan sponsor is unable to successfully complete the verification after the first attempt, then it must send the applicant the model education letter for use by all plan sponsors (which can be referenced at <http://www.cms.hhs.gov/PrivateFeeforServicePlans>). The plan sponsor must provide this letter in addition to any required enrollment notice, such as enrollment acknowledgement and confirmation letters. After the model education letter has been sent, the plan sponsor must make and document at least two additional attempts to successfully complete the verification. Plan sponsors must document verification activities as they will be subject to compliance audit by CMS or its contractors.

70.7 - Educational Events

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268(l), 423.2268(l)

Educational events are defined by the way in which an event is described to the Medicare beneficiary. An event hosted by the plan sponsor or an outside entity is considered an educational event if the event is advertised to beneficiaries as "educational."

Educational events may not include any sales activities such as the distribution of marketing materials or the distribution or collection of plan applications.

The intent of this guidance is not to preclude plan sponsors from educating beneficiaries about their products; rather, it is to ensure that events that are advertised as “educational” comply with CMS’ requirements. More specifically, plan sponsors may provide education at a sales or marketing event, but may not market or sell at an educational event.

The following are examples of acceptable materials for distribution and activities at an educational event:

- Materials provided that meet the CMS definition of education; that is, informing a potential enrollee about MA or other Medicare Programs, generally or specifically, but not steering, or attempting to steer, a potential enrollee towards a specific plan or limited number of plans. Specifically, any material distributed or made available to beneficiaries at an educational event must be free of plan-specific information (this includes plan-specific premiums, co-payments, or contact information), and any bias toward one plan type over another.
- A banner with the plan name and/or logo displayed (see §§40.7 and 50 for disclaimer guidance).
- Promotional items, including those with plan name, logo, and toll-free customer service number and/or website. Promotional items must be free of benefit information.
- A business card if the beneficiary requests information on how to contact the agent for additional information, as long as the business card is free of plan marketing or benefit information.

Plan sponsors or their representatives may not:

- Discuss plan-specific premiums and/or benefits;
- Distribute plan specific materials;
- Distribute or display business reply cards, scope of appointment forms, or sign-up sheets;
- Set-up personal sales appointments or get permission for an outbound call to the beneficiary;
- Attach business cards or plan/agent contact information to educational materials; however, upon a request by the beneficiary a business card can be provided; and
- Hold an educational event where participants are asked if they want information about a specific plan or limited number of plans.

The following are examples of events that are considered marketing events, and thus, all rules regarding marketing events apply:

- A plan sponsor advertises a presentation as educational, but after the presentation the agent asks if anyone would like to hear more about any specific options available to them. In this situation, the entire event would be considered marketing. Similarly, a plan sponsor may not advertise an educational event and then have a marketing event immediately following in the same general location (same hotel, for example).
- A plan sponsor conducts events where beneficiaries can get educational materials, a blood pressure check and enroll in the plan.
- An agent goes into a senior housing complex to talk about Original Medicare and/or Medigap policies, but then discusses an MA plan or PDP.
- An agent attends a community-sponsored health fair, and hands out plan-specific benefits information including premium and/or copayment amounts; or the agent hands out only educational materials but gives a brief presentation that mentions plan-specific premiums and/or copayment amounts.
- A SHIP hosts an event that is not advertised to beneficiaries as “educational.” A plan sponsor may be invited to discuss plan-specific benefits.

70.7.1 - Educational Event Disclaimer

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268(l), 423.2268(l)

CMS requires that the following disclaimer be used when an educational event is organized, sponsored or promoted by a plan and/or the plan participates in educational events.

"This event is only for educational purposes and no plan specific benefits or details will be shared."

This disclaimer is not required when a plan sponsor is invited to be a participant in an educational event sponsored, organized or promoted by an entity other than the plan sponsor.

70.8 - Health Fairs and Health Promotional Events

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268(l), 423.2268(l)

Health fairs and health promotion events are defined by the venue, the room design, and the way in which the event is advertised to the Medicare beneficiary. For example, health fairs and health

promotional events tend to have a more casual atmosphere and are typically held in convention centers, church basements, and gymnasiums. These events are typically comprised of various participant booths that are manned by staff to answer questions and hand out materials.

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

Sole-Sponsor, referring to a single-sponsor for an event; and

Multiple-Sponsor, indicating more than one sponsor for an event.

The following rules apply to both Sole-Sponsor and Multiple-Sponsor events. Please note that if a health fair or health promotional event is billed as educational then the plan sponsor must abide by the rules for an educational event as outlined in §70.7. Additional guidance specific to each type is provided under §70.7.

- Such events should be social and must not include a sales presentation.
- Plan sponsors or their representatives are expected to respond to questions asked at the event. Response by a plan sponsor's representative to questions asked at the event will not be considered a sales presentation as long as no enrollment form is accepted at the event.
- Advertisements for the event may be distributed to either enrollees, non-enrollees or both.
- The value of any give-away or free item including entertainment must be consistent with CMS' definition of nominal gift (cannot exceed \$15 per attending person, based on the retail purchase price of all items provided by the plan sponsor). For planning purposes, event budgets can be based on projected attendance. The cost of overhead for the event (e.g., room rental) is not included in the \$15 limit.
- Pre-enrollment advertising materials (including enrollment forms) can be made available.
- Enrollment forms cannot be accepted during these types of events, including the collection of completed enrollment forms.
- Meals may be provided at educational events only as provided in §70.2.1.

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

70.8.1 - Additional Sole Sponsor Policies

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

If offered, individual door prizes/raffles (including a combination of door prizes/raffles) cannot exceed the \$15 limit each, based on the retail purchase price of the item (please refer to §70.2 for further guidance). Disclaimers should be present to advise that there is no obligation to enter and/or be eligible for the door prizes/raffle.

70.8.2 - Additional Multiple-Sponsor Policies

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

A jointly sponsored event must consist of the plan sponsor and one or more sponsor participants who are not contracting providers with the organization. Door prizes/raffles can exceed the \$15 limit if a plan sponsor contributes no more than \$15 to a pool of cash for a prize or prizes such that no prize is individually identified with the plan sponsor, but is identified with a list of contributors. A disclaimer should be present to advise Medicare beneficiaries that there is no obligation to enroll in order to enter and/or be eligible for the door prizes/raffles.

A plan sponsor may also contribute cash toward prize money to a foundation or another entity sponsoring the event. (For example: A radio station, along with many sponsors, organizes a senior health fair). Anyone who attends may register for the door prize (for example, a weekend get-away).

The plan sponsor may participate in the fair, contribute to the door prize, and permit attendees to register for the prize at its booth (as well as other sponsor booths). However, the plan sponsor cannot claim to be the sole donor of the prize. It must be clear that the prize is attached to the event and not the individual organization.

70.8.3 Provider Participation in Health Fairs

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42CFR 422.2268(j) and (k), 423.2268(j) and (k)

Providers may only distribute marketing materials that compare the benefits of different health plans if they accept and display materials from all plan sponsors with which they contract. The use of publicly available comparison information approved by CMS is permitted.

70.9 - Marketing/Sales Events

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

Marketing/sales events are defined by both the range of information provided and the way in which that content is presented to the Medicare beneficiary. In addition, marketing/sales events are defined by the plan's ability to collect applications and enroll Medicare beneficiaries during the event. There are two main types of marketing/sales events – formal and informal. Plan Sponsors must upload all marketing/sales events in HPMS before the events take place. All sales events are open to the general public and to all Medicare beneficiaries.

Formal marketing/sales events are typically structured in an audience/presenter style with a sales person or plan representative formally providing specific plan sponsor information via a presentation on the products being offered. In this setting, the presenter usually presents to an audience that was previously invited to attend. The audience can be comprised of current members and prospective members, as well those attending on behalf of a Medicare beneficiary. At some time during a typical marketing/sales event information may be handed out, including enrollment applications. Enrollment applications may also be collected at such events. Presenters must announce all products that will be covered during any formal presentation at the beginning of that presentation.

Informal marketing/sales events depend less on a structured presentation to an audience. Instead, they typically utilize a table or kiosk manned by a plan sponsor sales person who can discuss the merits of the plan's products when approached by a Medicare beneficiary or someone on a Medicare beneficiary's behalf. For example, an informal marketing/sales event allows a sales person to proactively discuss the merits of a plan or plan(s) to an interested beneficiary, whereas at a health fair or health promotional event the plan sponsor representative may only reactively answer questions posed by the interested party.

Plan sponsor marketing of non-health care related products (such as annuities and life insurance) to prospective enrollees during any MA or Part D sales activity or presentation is considered cross selling and is a prohibited activity. Beneficiaries already face difficult decisions regarding Medicare coverage options and should be able to focus on Medicare options without confusion or implication that the health and non-health products are a package. Plans may sell non-health related products on inbound calls when a beneficiary requests information on other non-health products. Marketing to current plan members of non-MA plan covered health care products, and/or non-health care products, is subject to Health Insurance Portability and Accountability Act (HIPAA) rules.

In addition, the following information, which applies to both formal and informal sales/marketing events, further distinguishes these marketing events from the other types of events outlined by CMS in these guidelines.

At marketing events plan sponsors may:

- Distribute health plan brochures and pre-enrollment advertising materials;
- Accept and perform enrollments;

- Formally present benefit information to the audience via a scripted talk, electronic slides, handouts, etc.;
- If a beneficiary requests a one-on-one meeting then the beneficiary must fill out a scope of appointment for a subsequent meeting;
- Provide educational content to the audience or passersby; and
- Provide a nominal gift to attendees with no obligations (see §70.2 regarding nominal gift).

At marketing events, plan sponsors must:

- Clearly read or state the following disclaimer during PFFS presentations/events:
 - **“A Medicare Advantage PFFS plan works differently than a Medicare supplement plan. Your doctor or hospital is not required to agree to accept the plan’s terms and conditions, and thus may choose not to treat you, with the exception of emergencies. If your doctor or hospital does not agree to accept our payment terms and conditions, they may choose not to provide health care services to you, except in emergencies.”**
- Clearly explain the following during SNP presentations/events:
 - Eligibility requirements; and
 - Process for disenrollment if the beneficiary loses his/her Medicaid status (or becomes eligible for enrollment for a Chronic SNP).

At a marketing event, plan sponsors may not:

- Conduct health screening or other like activities that could give the impression of “cherry picking”;
- Compare one plan sponsor to another by name unless both plan sponsors have concurred; and
- Provide meals to attendees (see §70.2.1 on exclusion of meals).

All sales scripts and presentations must be submitted and approved by CMS prior to their use during marketing/sales events (Refer to §90 for additional information).

Plan sponsors must upload all marketing/sales events prior to the events’ scheduled date. Plan sponsors must upload an event no later than the 30th of the month preceding the event. Amendments to marketing/sales events (e.g. cancellations, updates and edits) must be updated in HPMS at least 48 hours prior to the scheduled event.

Plan sponsors should enter cancellations of marketing/sales events as soon as possible in the HPMS Marketing Module Cancel Event function. Please see the HPMS Marketing Module User Guides for details.

Plan sponsors must notify beneficiaries of cancelled events consistent with the following rules:

1. If the sales event is cancelled within 48 hours of its originally scheduled date and time, the plan must have a representative at the site of the cancelled sales event at the time the event was scheduled to occur to inform attendees of the cancellation and distribute information about the plan. The representative must remain for at least fifteen (15) minutes after the scheduled start time before leaving and must include signage stating that the event was cancelled. If appropriate, notice can include alternate event opportunities.
2. If the sales event is cancelled more than 48 hours prior to its originally scheduled date and time, the plan should notify beneficiaries of the cancelled event using the same means the plan used to advertise the event. Examples of reasonable notification are the following:
 - a. If an announcement of a sales event was made in the newspaper, then the cancellation of the event should also be announced through the same newspaper. If cancellation cannot be updated in the newspaper, plans must provide an alternative method for notifying beneficiaries (e.g., leave a post signage at the event of the cancellation).
 - b. If beneficiaries were identified through personal phone calls, then a representative of the plan should call the beneficiaries to inform them of the cancellation.
 - c. If beneficiaries sent a RSVPed for the event, then a representative from the plan should call the beneficiaries to inform them of the cancellation.
 - d. If the announcement of the sales event was through a mass mailing, the plan should consult with their Account Manager to determine a reasonable way to notify beneficiaries of the cancellation instead of sending another mass mailing within a short time frame.
 - e. Plan sponsors should save documentation related to the above cancellations types (a-d) and be prepared to provide a copy of the documentation to CMS upon request.
3. If an agent arrives at a scheduled event, the agent should remain at the event for at least 15 minutes after the scheduled time before leaving and must include signage stating that the event was cancelled due to non-attendance. If appropriate, notice should include alternate event opportunities.
4. If beneficiaries are notified of a cancelled event more than 48 hours prior to the originally scheduled date and time, the plan should not have a representative at the site of the event. Agents should attest that the event was cancelled and that beneficiaries were notified.

Notification documentation should include a list of beneficiary names and phone numbers and the date and time beneficiaries were notified. The plan is expected to keep the attestation on file and make it available upon CMS request.

70.9.1 - Additional Guidance for Marketing Events in the Provider Setting

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268(j) and (k), 423.2268 (j) and (k)

As used in specific guidance about provider activities, the term “provider” refers to all providers contracted with the plan and their sub-contractors, including but not limited to, pharmacists, pharmacies, physicians, hospitals, and long-term care facilities.

These guidelines are designed to guide plan sponsors and providers in assisting beneficiaries with plan selection, while at the same time striking a balance to ensure that provider assistance results in plan selection that is always in the best interest of the beneficiary. Providers that have entered into co-branding relationships with plan sponsors must also follow this guidance.

70.9.2 - Plan Activities and Materials in the Health Care Setting

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268(k), 423.2268 (k)

Plan sponsors may not conduct sales activities in healthcare settings except in common areas. Common areas where marketing activities are allowed include areas such as hospital or nursing home cafeterias, community or recreational rooms, and conference rooms. If a pharmacy counter area is located within a retail store, common areas would include the space outside of where patients wait for services or interact with pharmacy providers and obtain medications.

Plan sponsors are prohibited from conducting sales presentations, distributing and accepting enrollment applications, and soliciting Medicare beneficiaries in areas where patients primarily intend to receive health care services. These restricted areas generally include, but are not limited to, waiting rooms, exam rooms, hospital patient rooms, dialysis center treatment areas (where patients interact with their clinical team and receive treatment), and pharmacy counter areas (where patients interact with pharmacy providers and obtain medications). The prohibition against conducting marketing activities also applies after business hours in these settings. An example of such activity includes providers sending out authorization for disclosure form information to their members, such as nursing home members, to request that the member give permission for a plan sponsor to contact them about available plan products (through mailing, hand delivery or attached to an affiliation notice).

Only upon request by the beneficiary are plan sponsors permitted to schedule appointments with beneficiaries residing in long-term care facilities. Additionally, providers are permitted to make available and/or distribute plan marketing materials as long as the provider and/or the facilities distributes or makes available plan sponsor marketing materials for all plans with which the

provider participates. Providers are also permitted to display posters or other materials within the long-term care facility announcing all plan contractual relationships.

70.9.3 - Provider-Based Activities

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268(j), 423.2268(j)

CMS holds plan sponsors responsible for any comparative/descriptive material developed and distributed on their behalf by their contracting providers. The plan sponsor must ensure that any providers contracted (and its subcontractors, including providers or agents) with the plan sponsor comply with the requirements outlined in this chapter.

The plan sponsor must ensure that any providers contracted (and its subcontractors or agents) with the plan sponsor to perform functions on their behalf related to the administration of the plan benefit, including all activities related to assisting in enrollment and education, agree to the same restrictions and conditions that apply to the plan sponsor through its contract. In addition, the plan sponsor (and subcontractors, including providers or agents) are prohibited from steering, or attempting to steer an undecided potential enrollee toward a particular provider, or limited number of providers, offered either by the plan sponsor or another plan sponsor, based on the financial interest of the provider or agent (or their subcontractors or agents). While conducting a health screening, providers may not distribute plan information to their patients since this is a prohibited marketing activity.

CMS is concerned with provider activities for the following reasons:

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

Providers may face conflicting incentives when acting as a plan sponsor representative. For example, some providers may gain financially from a beneficiary's selection of one plan over another plan. Additionally, providers generally know their patients' health status. The potential for financial gain by the provider influencing a beneficiary's selection of a plan could result in recommendations that do not address all of the concerns or needs of a potential plan enrollee.

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

Providers are permitted to make available and/or distribute plan marketing materials and display posters or other materials announcing plan contractual relationships as long as providers offer this to all plans with which the provider participates.

All payments that plans make to providers for services must be fair market value, consistent for necessary services, and otherwise comply with all relevant laws and regulations, including the Federal and any State anti-kickback statute.

For enrollment and disenrollment guidance related to beneficiaries residing in long-term care facilities (e.g., enrollment period for beneficiaries residing in long-term care facilities and use of personal representatives in completing an enrollment application), please refer to Chapter 2 of the Medicare Managed Care Manual

Providers should remain neutral parties in assisting plan sponsors with marketing to beneficiaries or assisting with enrollment decisions. Providers not being fully aware of plan benefits and costs could result in beneficiaries not receiving information needed to make an informed decision about their health care options. Therefore, it would be inappropriate for providers to be involved in any of the following actions:

- Offering sales/appointment forms;
- Accepting enrollment applications for MA/MA-PD or PDPs;
- Directing, urging or attempting to persuade beneficiaries to enroll in a specific plan based on financial or any other interests;
- Mailing marketing materials on behalf of plan sponsors;
- Offering anything of value to induce plan enrollees to select them as their provider;
- Offering inducements to persuade beneficiaries to enroll in a particular plan or organization;
- Health screening when distributing information to patients, as health screening is a prohibited marketing activity; and
- Accepting compensation directly or indirectly from the plan for beneficiary enrollment activities.

Providers contracted with plan sponsors (and their contractors) are permitted to do the following:

- Provide the names of plan sponsors with which they contract and/or participate (see §70.9.4 for additional information on affiliation);
- Provide information and assistance in applying for the low income subsidy;

- Provide objective information on ALL plan sponsors' specific plan formularies, based on a particular patient's medications and health care needs;
- Provide objective information regarding ALL plan sponsors' specific plans being offered, such as covered benefits, cost sharing, and utilization management tools;
- Distribute all PDPs' marketing materials with whom the provider contracts with, including enrollment application forms;
- Make available and/or distribute plan marketing materials for all plans with which the provider participates (including PDP enrollment applications, but not MA or MA-PD enrollment applications);
- Refer their patients to other sources of information, such as the SHIPS, plan marketing representatives, their State Medicaid Office, local Social Security Office, CMS's website at <http://www.medicare.gov/>, or calling 1-800-MEDICARE; and
- Print out and share information with patients from CMS's website.

The "Medicare and You" Handbook or "Medicare Options Compare" (from <http://www.medicare.gov>), may be distributed by providers without additional approvals. There may be other documents that provide comparative and descriptive material about plans, of a broad nature, that are written by CMS or have been previously approved by CMS. These materials may be distributed by plan sponsors and providers without further CMS approval. This includes CMS Plan Finder information via a computer terminal for access by beneficiaries. Plan sponsors should advise contracted providers of the provisions of these rules.

70.9.4 - Provider Affiliation Information

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

Providers may announce new affiliations and repeat affiliation announcements for specific plan sponsors through general advertising (e.g., publicity, radio, television). An announcement to patients of a new affiliation which names only one plan sponsor may occur only once when such announcement is conveyed through direct mail and/or email. Additional direct mail and/or email communications from providers to their patients regarding affiliations must include all plans with which the provider contracts. Provider affiliation banners, displays, brochures, and/or posters located on the premises of the provider must include all plan sponsors with which the provider contracts. Any affiliation communication materials that describe plans in any way (e.g., benefits, formularies) must be approved by CMS. Multiple plan sponsors can either have one plan sponsor submit the material on behalf of all the other organizations, or have the piece submitted and approved by CMS for each plan sponsor mentioned prior to use. Materials that indicate the

provider has an affiliation with certain plan sponsors and that only list plan names and/or contact information do not require CMS approval.

70.9.5 - SNP Provider Affiliation Information

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

Providers may feature SNPs in a mailing announcing an ongoing affiliation. This mailing may highlight the providers' affiliation or arrangement by placing the SNP affiliations at the beginning of the announcement and may include specific information about the SNP. This includes providing information on special plan features, the population the SNP serves or specific benefits for each SNP. The announcement must list all other plans with which the provider is affiliated.

70.9.6 - Comparative and Descriptive Plan Information

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

Providers may distribute printed information provided by a plan sponsor to their patients comparing the benefits of all of the different plans with which they contract. Materials may not "rank order" or highlight specific plans and should include only objective information. Such materials must have the concurrence of all plan sponsors involved in the comparison and must be approved by CMS prior to distribution (e.g., these items are not be subject to File & Use). The plan sponsor must determine a lead plan to coordinate submission of these materials (See §90.2 for more information).

NOTE: Plan sponsors may not use providers to distribute printed information comparing the benefits of different plans unless providers accept and display materials from all plan sponsors in the service area and contract with the provider.

70.9.7 - Comparative and Descriptive Plan Information Provided by a Non-Benefit/Service Providing Third-Party

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

Providers may distribute printed information comparing the benefits of different plan sponsors (all or a subset) in a service area when the comparison is done by an objective third party. For more information on non-benefit/service providing third party providers see §40.14.6.

70.9.8 - Providers/Provider Group Websites

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

Providers may provide links to plan enrollment applications and/or provide downloadable enrollment applications. The site must provide the links/downloadable formats to enrollment applications for all plan sponsors with which the provider participates. As an alternative, providers may include a link to the CMS Online Enrollment Center.

NOTE: The preceding requirement is not required for certain plan types such as 1876 Cost Plans, Medicare MSAs, 800-Series employer group waiver plans, and Religious Fraternal Benefit plans. SNPs have the option to use the links, and the SNP should notify the provider that they may use the OEC link if they choose to but it is not required.

70.10 - Personal/Individual Marketing Appointments

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

Personal/individual marketing appointments are defined by the intimacy (e.g., setting of where the appointment takes place). Personal/individual marketing appointments typically take place in the Medicare beneficiary's home, however, these appointments can also take place in other venues such as a library or coffee shop.

If the appointment was set up in accordance with the scope of appointment guidance provided in the next section, the sales person may:

- Distribute plan materials;
- Discuss various plan options;
- Provide educational content; and
- Provide and collect enrollment forms.

The sales person, however, may not do the following:

- Discuss plan options that were NOT agreed to by the Medicare beneficiary (see scope of appointment in §70.10.1);
- Market non-health care related products (such as annuities and life insurance).

70.10.1 - Scope of Appointment

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268(g) and (h)

In conducting marketing activities, an MA or Part D plan sponsor may not market any health care related product during a marketing appointment beyond the scope agreed upon by the beneficiary, and documented by the plan, prior to the appointment. Distinct lines of plan business include Medigap, MA, and PDP products.

The scope of appointment must be agreed to by the Medicare beneficiary prior to any face-to-face personal/individual marketing appointment. Agents and brokers can document the scope of appointment in writing via a scope of appointment form or by recording a phone call in advance of the appointment. The sales person is bound to only discuss those products that have been agreed upon by the beneficiary during that appointment. If other products need to be discussed at the request of the beneficiary, a second scope of appointment form must be completed for the new product type and then the marketing appointment may be continued.

For example, if a beneficiary has agreed to an in-home appointment to discuss a PDP product, an agent can discuss an HMO product with them during that same meeting, if the beneficiary requests it and a new scope of appointment form is completed. To further clarify the requirements around written documentation:

- Plan sponsors must secure scope of appointment documentation prior to the appointment. A beneficiary cannot agree to the scope over the phone (unless it is recorded) and then sign the documentation form at the beginning of the sales appointment. If a plan/agent does not have phone recording capability, a form may be mailed to the beneficiary that can be returned as written documentation. Any scope of appointment form must be completed by the beneficiary and returned prior to the appointment. If it is not feasible for the scope of appointment form to be executed prior to the appointment, an agent may have the beneficiary sign the form at the beginning of the marketing appointment.
- The documentation must be in writing, in the form of a signed agreement by the beneficiary, or a recorded oral agreement. A plan sponsor or agent documenting the agreement is not acceptable, whether done in writing or using an electronic contact documenting system.
- Plan sponsors are allowed and encouraged to use a variety of technological means to fulfill the scope of appointment requirement, including conference calls, fax machines, designated recording line, pre-paid envelopes, e-mail, etc.
- A beneficiary may sign a scope of appointment form at a marketing presentation for a follow-up appointment. In these instances, the 48 hour waiting period does not apply. For example, if a beneficiary attends a marketing presentation, and, upon the conclusion of the presentation, requests an individual appointment, the sales person can arrange for that appointment to take place immediately following the sales presentation, provided the beneficiary has completed the scope of appointment form.

Marketing/sales events, as described in §70.9 do not require documentation of beneficiary agreement because the scope of products that will be discussed should be indicated on all event

advertising materials. CMS has developed a model scope of appointment form which can be found at http://www.cms.hhs.gov/ManagedCareMarketing/09_MarketngModelsStandardDocumentsandEducationalMaterial.asp#TopOfPage). Written scope of appointment forms must be submitted for CMS approval (Category 4000, Code 4011). We encourage plan sponsors to use our model scope of appointment form, and use of the model without modification may be submitted under File & Use. A modified form must be submitted for 45-day review. If the scope of appointment is gathered via a recorded phone call the plan sponsor must ensure that any associated scripts for such calls must be submitted to and approved by CMS prior to their use.

The record retention requirements for all documentation related to MIPPA implementation are the same as those that pertain to other similar Medicare areas (i.e., enrollment) of the current contract period, including ten (10) prior periods (see 42 CFR 422.504(e)(4); 42 CFR 423.2260).

70.10.2 - Beneficiary Walk-ins to a Plan or Agent/Broker Office or Similar Beneficiary-Initiated Face-to-Face Sales Event

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268(g) and (h), 423.2268 (g) and (h)

In instances where a beneficiary visits a plan or an agent/broker office on his/her own accord, the plan sponsor or agent/broker should complete a scope of appointment form and secure the beneficiary's signature prior to discussing MA or PDP plans. Plan sponsors and agents/brokers should note on the scope of appointment form that the beneficiary was a walk-in. In this instance, the 48 hour waiting period does not apply.

70.11 - Specific Guidance on Outreach to Dual Eligible Members

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264(a)(4), 423.2264(a)(3)

This section provides guidance to plan sponsors on dual eligible outreach program requirements and the process for submitting outreach program details and outreach materials (e.g., letters, call scripts) to CMS for approval. In addition, this section also provides CMS staff with operating procedures for reviewing and approving the outreach programs.

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

- The individuals equate Medicaid with Welfare and associate a social stigma with the terms;

- They are not aware of the savings that are available;
- They do not understand the eligibility requirements; or
- They find the process sometimes complex and difficult to understand.

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

70.11.1 - Guidance on Dual Eligibility

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264(a)(4), 423.2264(a)(3)

There are several categories of dual eligibility, each having specific income requirements and providing different levels of financial assistance to those who qualify at that level. Specific information on categories and amounts are available at <http://www.cms.hhs.gov/DualEligible/>.

70.11.2 - Guidance for Dual Eligible Outreach Program

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264, 422.2268, 423.2268

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

The plan sponsors must:

- Provide outreach to all levels of dual eligibles, including those levels that do not provide plan sponsors with additional capitation amounts from CMS. All outreach materials and telephone scripts must include eligibility information that includes the QI-1 level as described at <http://www.cms.hhs.gov/DualEligible/>;
- Clarify in outreach materials that the member may voluntarily offer information, including financial information, but that the member is not obligated to provide this information. However, for SNP enrollment this information is needed to confirm eligibility;
- Clarify in outreach materials and discussions with members that the member's failure to provide information will in no way adversely affect the beneficiary's

membership in his or her health plan but may be needed to confirm eligibility for a SNP;

- Clarify in outreach materials, to include member letters, that the Medicare Savings Programs are part of either the “State Medicaid program” or “State medical assistance programs”;
- State in materials and discussions with members that the plan sponsor will not share the information with any other entity not directly associated with determining eligibility or under contract to participate in the outreach process;
- Clarify in outreach materials that the plan sponsor is only providing an initial eligibility screening and that only the appropriate State Agency can make a final eligibility determination;
- Provide guidance to a member on how to proceed with the application process even if the plan sponsor’s screening process indicates that the member is probably not eligible for assistance under any of the dual eligibility programs;
- Provide adequate training to staff conducting the outreach. If the plan sponsor subcontracts this effort to another entity, it must ensure that the subcontractor’s staff is adequately trained to provide outreach;
- Include alternate sources of information in outreach materials. Member letters and/or brochures that contain outreach information telephone numbers must also include the telephone number for beneficiaries to call the SHIP and the appropriate State Agency. Outreach materials may also include the telephone number for the 1-800-MEDICARE (1-800-633-4227) and the TYY number for Medicare (1-800-486-2048);
- Include privacy guidelines in outreach materials, telephone scripts, and internal processes and/or contracts with entities performing outreach for the plan sponsor. Contractual privacy guidelines must clearly state that all financial information collected from members of the plan sponsor will not be used for any other purpose by the entity collecting the data. Privacy guidelines must also state that entities involved in the outreach will not share member information with anyone not involved in the outreach process
- Ensure that contracts with entities taking part in some aspect of outreach activities meet Medicare Advantage Administrative Contracting requirements listed in the Medicare Managed Care Manual, Chapter 11, and §100.5.
- Work closely with CMS’s regional office staff during the outreach submission and review process so that CMS can work cooperatively with stakeholders (e.g., SHIPs, State Agency) to ensure better education and preparation prior to the outreach process initiation.

The plan sponsor may:

- Conduct outreach for only a portion of its plan membership. Selection of the focus population may be based upon demographic data and/or may focus on a specific geographic area. However, the plan sponsor must provide outreach to all individuals within those pre-identified population segments. Additionally, if the plan sponsor receives an inquiry from a plan member not previously identified in the targeted group, it must provide assistance to that member as if he or she had been included in the initial group;
- Provide hands-on assistance to the member in completing all necessary applications for financial assistance including submitting the paperwork to the appropriate State office. This assistance can be in the member's home only if the member requests such a visit;
- Use the "Authorization to Represent" form limited to the specific purposes of completing and submitting paperwork on behalf of the member, discussing the member's case with case workers, and gathering information from and on behalf of the plan sponsor's member. The "Authorization to Represent" form must specify that the authorization is limited to securing benefits under "the Medicare Savings Program" or "the Medicaid Program" and cannot extend to other programs unless agreed upon and noted by the member. "Authorization to Represent" shall not give the outreach specialist the authority to sign any documents on behalf of the member, make any enrollment decisions for the member, or file a grievance or request an initial decision (coverage determination) or appeal on a member's behalf;
- Follow up with members who do not respond to the initial member letter. This follow-up may be in the form of a second and/or third letter or telephone calls. If the member does not respond to the third effort, the plan sponsor must refrain from contacting the member for at least 6 months following the last outreach attempt;
- Provide assistance to members reapplying for financial benefits if and when required to do so by the Medicaid State agency; and
- Subcontract all outreach efforts to another entity or entities. In such cases, while the plan sponsor retains all responsibility for meeting CMS's requirements, it must still submit all documentation to the appropriate CMS Regional Office for approval including contracts held by the subcontractor with all entities related to the program. The plan sponsor must also coordinate changes and revisions between the subcontractor and CMS.

The plan sponsor must not:

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

- Share any member information, financial or otherwise, with any entity not directly involved in the outreach process;
- Store or use member financial information for any purpose other than the initial screening eligibility, the submission and follow-up of an application for benefits, for recertification purposes, and as required by law;
- Contact any member who has refused outreach assistance or who has not responded to the telephone call or follow-up letter until at least six months following the last outreach attempt; and
- Imply in any written materials or other contact with the member that the organization has the authority to determine the member's eligibility for State assistance programs.

70.11.3 - Outreach Submission Requirements

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

To facilitate CMS's review of outreach programs, a plan sponsor must submit one hard copy and one electronic copy of the materials listed below to the Regional Office Account Manager.

1. A detailed description of each step in the outreach process and the entity responsible for each step. (CMS recommends a flow chart showing the result of each action.)
2. A timeline showing the proposed dates of outreach activities, the number of members involved in each activity, and the service area (e.g., county) included in the activities. This is to allow CMS to more accurately coordinate outreach activities with its partners (e.g., SHIPS, State Agencies).
3. Executed contracts with all external entities involved in the outreach process. This includes contracts with any subcontractors taking part in the activities.
4. Supporting documentation from the appropriate State Agency providing specific State income requirements for each savings program level, and names and contacts within the appropriate State Agency/agencies.
5. Outreach letters and other materials (e.g., brochures, Authorization to Represent form) going to plan sponsor members.
6. Internal training programs the organization is using to educate staff involved in outreach.
7. Telephone scripts or other outreach assistance scripts that will guide representatives in answering members' questions or discussing the assistance available to them. Such scripts must include a privacy statement clarifying that the member is not required to provide any information to the representative and that the information provided will in no way affect the beneficiary's membership in the plan.

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

In some instances, a plan sponsor may choose to submit an outreach proposal that CMS has already approved for use by another plan sponsor. This is common when a plan sponsor is part of a national organization with multiple contracts, each of which is conducting its own outreach. This is also common when a subcontracting entity designs and conducts the outreach and then contracts with multiple plan sponsors to conduct the same outreach programs for each of their clients.

If an plan sponsor submits an outreach proposal that CMS previously approved on or after April 1, 2002 that does not contain substantive changes to qualify it as an "initial" proposal, the plan sponsor must submit the items listed above (1 - 8) in addition to the following:

- The plan sponsor must submit an attestation from either the plan sponsor or its contracted outreach vendor stating:
 - that the proposal has been approved by CMS,
 - the date of that approval, and
 - that the new submission does not contain substantive changes to the approved program.

70.11.4 - CMS Review/Approval of Outreach Process

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

The CMS review process for new outreach proposals differs from the review process for previously approved outreach proposals. The processes for both submissions are stated below at §70.11.5.

70.11.5 - Reviewing New Outreach Programs

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 422.2264, 422.2268, 423.2262, 423.2264, 423.2268

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

Because CMS considers outreach materials to be a form of marketing, CMS will review outreach proposals according to current time frames for reviewing marketing material. CMS will conduct its initial review and provide comments to the plan sponsor within 45 days of receipt of a new (not previously approved) proposal. At this time, the plan sponsor should not submit this material through HPMS but as a separate filing outside the “normal” marketing material submission process.

Plan sponsors must submit one complete copy (paper and electronic) of the materials to the CMS Regional Office Account Manager. If a proposal incorporates States in Regions other than those represented above, the Regional Office Account Manager will coordinate the review with the other affected Regions and the CMS State Representative for those State(s).

The Regional Office Account Manager will relay CMS comments back to the plan sponsor, gather revisions (when necessary), and finish the review and approval process based upon the plan sponsor’s revisions. The Regional Office Account Manager will share outreach materials with the appropriate CMS State Representatives. The CMS State Representatives should, at a minimum, share the member letters with the State Agency as a way to verify the accuracy of the information contained in the proposal and to receive input from State partners. Upon final approval of the proposal and outreach materials, the Regional Office Account Manager will send an approval letter to the plan sponsor.

The Regional Office will then contact its partners (SHIPS, State Medicaid Offices) to notify them of the outreach effort and possible increase in beneficiary inquiries. The Regional Office will share copies of outreach letters with the State Agencies to prepare them for incoming questions.

70.11.6 - Reviewing Previously Approved Outreach Programs

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

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

If the plan sponsor wishes to make substantive changes to the outreach process, it must submit those changes to the appropriate CMS Regional Office Account Managers for review according to the review process above.

70.12 - PFFS Plan Provider Education and Outreach Programs

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.114(a)(1)

CMS strongly encourages all PFFS plan sponsors to develop and implement a provider education and outreach program to encourage a wide range of providers to accept PFFS enrollees. PFFS plan sponsors must develop provider relation strategies, a provider education process, and educational materials that include establishing relationships with and educating providers in the PFFS plan's service area. PFFS plan sponsors must conduct effective outreach to providers to help them understand how PFFS plans work and to overcome any resistance that may be particularly caused by concerns about the timeliness and accuracy of payments. In order to address these issues, PFFS plan sponsors must ensure that they clearly inform providers about how to obtain their terms and conditions of payment, how to get payment or coverage questions quickly answered, and how to appeal payment decisions.

Listed below are examples of practices that CMS encourages PFFS plan sponsors to incorporate in their provider education and outreach programs. There may be other approaches that PFFS plan sponsors may utilize in order to develop provider education and outreach programs.

- Use the appropriate staff (e.g., provider relations specialists) to educate providers in the plan's service area and State provider associations (e.g., medical and hospital associations).
- Furnish a provider educational material packet to providers who contact the plan for information. The contents of the provider education material packet could include the plan's terms and conditions of payment, the beneficiary/provider education leaflet and the CMS provider education letter. Refer to the web link <http://www.cms.hhs.gov/PrivateFeeforServicePlans/>.
- Furnish a provider educational material packet to providers within the plan sponsor's service area who have not already received a packet, upon receipt of the first claim.
- Develop a process to obtain current provider information from prospective and current enrollees and proactively contact and educate the enrollee's current providers. These providers can be furnished with a provider educational material packet.
- Ensure the beneficiary/provider education leaflet is widely available to enrollees, so that they may in turn furnish it to their providers.
- Non-network PFFS plan sponsors have the option of establishing direct contracts under which providers agree in advance to treat plan members and accept the plan's terms and conditions of payment. PFFS plan sponsors that establish payment rates less

than Original Medicare must have direct contracts with sufficient providers in order to meet Medicare access requirements under federal regulations at 42 CFR 422.114(a)(2)(ii) or (a)(2)(iii). However, PFFS plan sponsors that have met Medicare access requirements by establishing payment rates at or above Original Medicare may also establish direct contracts with providers. In this case, the plan sponsor establishes provider contracts not to meet Medicare access requirements, but rather to ensure enrollees that they will have access to providers who will agree to accept the PFFS plan.

Adequate participation by providers is critical to the success of the PFFS program; thus plan sponsors should focus on increasing outreach to providers and educating them about how PFFS plans work. To encourage provider participation, plan sponsors must ensure that providers have reasonable access to their terms and conditions of payment and that those providers are being paid correctly and timely. CMS will be closely monitoring beneficiary and provider complaints and other marketplace-based information to determine whether compliance and/or enforcement actions are warranted. CMS may require that PFFS plan sponsors with documented provider access problems provide CMS data about their provider education and outreach efforts.

70.12.1 - PFFS Plan Staff Requirement for Assisting Providers

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.114

PFFS plan sponsors are required to have staff available to assist providers with questions concerning plan payment and payment accuracy. CMS encourages PFFS plan sponsors to better educate their provider relations staff on the rules of their terms and conditions of payment so that they can provide reliable information to providers accurately and quickly. Plan sponsors must be committed to providing accurate information to providers that is also easily accessible. For example, providers should be able to obtain accurate information on member cost sharing amounts (including applicable deductibles) and plan payment rates when they call the plan. PFFS plan sponsors should address in a timely manner any inadequate capacity of plan contacts, such as excessive busy signals or excessive lack of timely response to voicemail messages.

70.12.2 - PFFS Plan Terms and Conditions of Payment Contact and Website Fields in HPMS

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.114

Fields are available in HPMS to allow MAOs offering PFFS plans to directly provide CMS with their plan terms and conditions of payment provider contact information. All PFFS plan sponsors must complete the data entry for these fields in HPMS and update the information as needed.

CMS has added the following contact field in HPMS for PFFS plan sponsors: “PFFS Terms and Conditions of Payment Contact for Public website”. Note that this field should be populated with

the contact that will facilitate provider access to the MAO's PFFS plan terms and conditions of payment. Use the following navigation path in HPMS to enter the appropriate information for this new contact: HPMS Homepage > Contract Management > Contract Management > Select a Contract Number > Contact Data.

CMS has also added the following website field in HPMS for PFFS plans: "PFFS Terms and Conditions of Payment website". Note that this field should be populated with the web address for where the MAO maintains its PFFS plan terms and conditions of payment. Use the following navigation path in HPMS to enter the appropriate information for this new contact: HPMS Homepage > Contract Management > Basic Contract Management > Select a Contract Number > Org. Marketing Data.

70.13 - Requirement that All Plans Give Beneficiaries Notice of Sales Event Cancellations

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.114

CMS has established the following requirements on how all plan sponsors should notify beneficiaries when advertised scheduled sales events have been cancelled. The method used to notify beneficiaries of the cancellation may vary depending on the individual plan's circumstances.

1. If a sales event is cancelled within 48 hours before of its originally scheduled date and time, the plan sponsor must:
 - Notify its Regional Office Account Manager of the cancellation.
 - A representative of the plan sponsor must be present at the site of the cancelled sales event, at the time that the event was scheduled to occur, to inform attendees of the cancellation and distribute information about the plan sponsor.
2. If a sales event is cancelled more than 48 hours of its originally scheduled date and time, the plan sponsor must notify its Regional Office Account Manager and beneficiaries of the cancellation by the same means the plan sponsor used to advertise the event. Examples of reasonable notification are:
 - If an announcement of the sales event was made in the newspaper, then the cancellation of the event must also be announced through the same newspaper;
 - If beneficiaries were identified through personal calls, then a representative of the plan sponsor must call the beneficiaries to inform them of the cancellation;
 - If beneficiaries RSVP for the sales event, then a representative of the plan sponsor must call the beneficiaries to inform them of the cancellation; and

- If an announcement of the sales event was sent through a mass mailing, then the plan sponsor should consult with the Regional Office to decide upon the most reasonable way to notify beneficiaries about the event cancellation in a short amount of time instead of a sending another mass mailing.

Notification of cancelled sales events should be made, whenever possible, more than 48 hours prior to the originally scheduled date and time of the event. If beneficiaries are notified of a cancellation more than 48 hours before the event, then there is no expectation that a representative of the plan sponsor should be present at the site of the event.

80 - Special Guidance on Telephonic Scripts and Activities

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

80.1 - Customer Service Call Center Requirements

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.128(d)(1)

During the annual enrollment period (November 15 to December 31 of each year) through 60 days past the beginning of the following calendar year (January 1 to March 1), plan sponsors will be required to operate a toll-free call center for both current and prospective enrollees that operates seven days a week at least from 8:00 A.M. to 8:00 P.M. according to the time zones for the regions in which they operate. During this time period, current and prospective enrollees must be able to speak with a customer service representative.

However, from March 2 until the following annual enrollment period, plan sponsors are permitted to use alternative technologies to meet the customer service call center requirements for Saturdays, Sundays, and holidays. For example, a plan sponsor may use an interactive voice response system or similar technologies to provide the required information listed below, and/or allow a beneficiary to leave a message in a voice mail box. A customer service representative must then return the call in a timely manner, within no more than one business day later.

The call center must:

- Provide information in response to inquiries outlined in §80.1.3;
- Follow an explicitly defined process for handling customer complaints;
- Provide service to all non-English speaking and hearing impaired beneficiaries; and
- Make information about Best Available Evidence (BAE) policy readily available for those who contact the plan sponsor's call center. Refer to §100 for additional information.

The call center must meet the following operating standards:

- Average hold time must not exceed 2 minutes. The average hold time is defined as the average time spent on hold by a caller following an interactive voice response (IVR) system and before reaching a live person;
- Eighty percent of incoming calls must be answered within 30 seconds; and
- Disconnect rate of all incoming calls must not exceed 5 percent.

80.1.1 - Pharmacy Technical Help Call Center

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.128(d)(1)

Plan sponsors offering Part D coverage must operate a toll-free pharmacy technical help call center or make available call support to respond to inquiries from pharmacies and providers regarding the beneficiary's Medicare prescription drug benefit. This requirement can be accommodated through the use of on-call staff pharmacists or by contracting with the organization's PBM during non-business hours as long as the individual answering the call is able to address the call at that time. Inquiries will concern such operational areas as claims processing, benefit coverage, claims submission and claims payment. The call center or call support must operate or be available during the entire period in which the plan sponsor's network pharmacies in its plans' service areas are open.

Please note that plan sponsors whose pharmacy networks include 24 hour pharmacies must operate their pharmacy technical help call centers 24 hours a day as well.

The call center must meet the following operating standards:

- Eighty (80) percent of incoming calls must be answered within 30 seconds;
- Disconnect rate of all incoming calls must not exceed 5 percent; and
- Average hold time must not exceed 2 minutes. The average hold time is defined as the average time spent on hold by a caller following an interactive voice response (IVR) systems and before reaching a live person.

80.1.2 - Coverage Determinations and Appeals Call Center

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.128(d)(1) 423.566(a)

Plan sponsors must operate a toll-free call center to respond to physicians and other providers for information related to coverage determinations (including exceptions and prior authorizations),

and beneficiary Part D appeals. The call center must operate during normal business hours and never less than from 8:00 a.m. to 6:00 p.m., Monday through Friday, according to the time zones for the regions in which they operate. Plan sponsors are expected to accept requests for coverage determinations/redeterminations outside of normal business hours, but are not required to have live customer service representatives available to accept such requests outside normal business hours. Additional details are available in Chapter 18 of the Prescription Drug Benefit Manual.

Voicemail may be used provided the message:

- Indicates that the mailbox is secure;
- Lists the information that must be provided so the case can be worked (e.g., provider identification, beneficiary identification, type of request (coverage determination or appeal), physician support for an exception request, and whether the member is making an expedited or standard request;
- For coverage determination calls (including exceptions requests) articulates and follows a process for resolution within 24 hours of call for expedited requests, and 72 hours for standard requests;
- For appeals calls, information should articulate the process information needed and provide for a resolution within 72 hours for expedited appeal, requests, and 7 calendar days for standard appeal requests; and
- Provides and follows a process for immediate access in situations where an enrollee's life or health is in serious jeopardy.

80.1.3 - Required Inbound Informational/Customer Service Telephone

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

Inbound informational/customer service telephone scripts are considered marketing materials and are subject to all requirements in this section and other relevant sections of the marketing guidelines.

NOTE: Plan sponsors are not required to collect a beneficiary's medication and pharmacy information to calculate an estimated total annual cost for various plans during a customer service telephone call.

At a minimum, plans must develop scripts to respond to existing and prospective enrollees for the situations listed below. Plan sponsors must submit to CMS only scripts noted with an asterisk (*) for review and approval; all others must be maintained by the plan sponsor.

- Request for pre-enrollment information (see §§30.9.1 and 50.4).*

- Request for post-enrollment information (see §40.13).*
- Responses to inquiries on at least the following topics:
 - Benefits;*
 - Service area;
 - Cost-sharing;*
 - Formulary;*
 - Network pharmacies, including whether a prospective enrollee’s pharmacy is in the plan sponsor’s network:
 - Provider networks, including whether a prospective enrollee’s primary care physician is in the plan sponsor’s network.
 - Out-of-network coverage;*
 - Claims submission;*
 - Formulary transition process;*
 - How to access the Part D grievance, coverage determination (including exceptions) and appeals process;*
 - Claims processing;
 - Benefit coverage;
 - How to obtain extra help;
 - Claims payment;
 - Current TROOP status;
 - How to obtain needed forms; and
 - How to replace a member identification card

NOTE: Telephone enrollment scripts are not considered “Informational Inbound Telephone Scripts” but are discussed under “*Enrollment via Inbound Telephone*”. (Refer to §80.2).

Plan Sponsors are not permitted to:

- Request prospective beneficiary identification numbers (e.g., Social Security Number, bank account numbers, credit card number, HICN) as part of pre-enrollment inbound informational scripts (except when determining an individual's eligibility to join a SNP) or member specific scripts requesting a beneficiary's member ID number.
- Include information about other lines of business as part of the inbound script. However, scripts can ask if the caller would like to receive information about other lines of business offered by the plan sponsor.
- Direct the caller to the enrollment area.

Informational inbound telephone scripts must be submitted for review and approval as an entire script, talking points, or bullet points. If scripts are submitted as talking points or bullet points, the material must clearly delineate acceptable language and practices from prohibited language and practices.

In developing and submitting scripts, plan sponsors must:

- Include the purpose of the script in the heading (e.g., advertising, benefit information, post-enrollment information, or situational responses).
- Include the applicable Federal contracting statement. Plan sponsors must ensure that the language does not imply that they are endorsed by Medicare or are answering on behalf of Medicare.
- Include all required language contained in the marketing guidelines that is appropriate to the purpose of the script (e.g., contain all relevant disclaimers as outlined in section 50.1).
- Include a privacy statement clarifying that the beneficiary is not required to give any information other than contact information to the CSR and that the information provided will not affect the beneficiary's ability to enroll or his/her membership in the plan.
- Use verbal responses to questions that follow the same guidelines required for similar printed materials in the same situation.
- Provide TTY numbers in conjunction with all other phone numbers.
- Include a greeting that can be delivered by either a Customer Service Representative (CSR) or an Interactive Voice Response (IVR). Greetings must:
 - Clearly state the plan name, the name of the programs being represented, and a brief description of the plan (e.g., a Medicare Prescription Drug plan, a Medicare Advantage plan). If voice prompts are used for this purpose, all choices and access directions must be clearly stated. Options should include a re-play option and an opt-out to a CSR option. In addition, an after-hours voice mail prompt must be provided.

- Provide options to access general information, enrollment information, or customer service. These options can be provided by either a CSR or an IVR. These options must be made available immediately after the plan name announcement. Under no circumstances can callers be connected directly to an enrollment specialist.
- Repeat the option that is selected by the caller (e.g., “Thank you for selecting general information” or “I can help you with general information”). If an IVR is used, opt-out options must be noted immediately after this announcement (e.g., “If this is not the information you want, press or say 1 to return to the main menu. Or, if you would like to speak to a customer service representative, press or say 4”).
- Clearly request the caller’s consent when advocating follow-up calls. Use of phrases such as “would you like” or “may we” are acceptable. Phrases such as “we will” are not acceptable. (Please see section 70.4 on unsolicited contacts for additional information)
- Use the appropriate disclaimer preceding the Value-Added Items and Services (VAIS) information, if applicable (See section 110).
- Always close by offering to send follow-up materials (published information). Directing callers to the plan sponsors website is optional.

80.2 - Enrollment via Inbound Telephone

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.60(c), 423.32(b)

Plan sponsors may accept enrollment requests via an incoming (inbound) telephone call to a plan sponsor’s representative or agent. Telephonic enrollment scripts and processes must follow the guidance provided in §40.1.4 of Chapter 2 of the Medicare Managed Care Manual and §30.1.3 of Chapter 3 of the Prescription Drug Benefit Manual.

Plans sponsors are not permitted to:

- Conduct outbound telephone enrollment.
- Transfer outbound calls to inbound lines for telephonic enrollment.
- Market or enroll other lines of business as part of the telephonic enrollment script.
- Request or collect credit card numbers or bank account information for any purpose during the telephonic enrollment call.

Telephonic enrollment scripts must be submitted in their entirety for review and approval. If scripts are submitted as talking points or bullet points, the material must clearly delineate

acceptable language and practices from prohibited language and practices. In developing and submitting scripts, plan sponsors must:

- Clearly state that the individual is requesting enrollment into [plan name] and the plan type.
- Comply with, at a minimum, all applicable requirements described in the CMS eligibility and enrollment guidance in §40.1.4 of Chapter 2 of the Medicare Managed Care Manual and §30.1.3 of Chapter 3 of the Prescription Drug Benefit Manual.
- Although not part of the telephonic enrollment request, plan sponsors may close the call with:
 - An offer to send or provide confirmation of having accepted the telephonic enrollment request, such as a confirmation tracking number;
 - A summary of the plan into which the individual has requested enrollment;
 - A statement that the individual will receive a notice acknowledging the plan sponsor's receipt of the completed enrollment election or requesting additional information;
 - Contact information for questions including toll free telephone and TTY numbers.

80.3 - Telephonic Sales Scripts

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 422.2264, 422.2268, 423.2262, 423.2264, 423.2268

Any telephonic sales scripts (inbound or out-bound) must be submitted verbatim to CMS for review. Plan sponsors should incorporate all needed disclaimers as found in §50.1, as well as all other relevant requirements as outlined in these guidelines. For outbound scripts (refer to §70.5), plan sponsors are reminded to pay close attention to the guidance on marketing through unsolicited contacts which extends to all downstream contractors.

In-bound sales scripts must clearly inform the beneficiary if/when the nature of the call moves from sales presentation to telephonic enrollment. This must be done with the full and active concurrence of the Medicare beneficiary, ideally with a yes or no question.

When conducting outbound calls:

- 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 determination of a beneficiary's eligibility for enrollment in the plan (except when verifying eligibility for an MSA).

- Plan sponsors are prohibited from requesting beneficiary identification numbers (e.g., Social Security Numbers, bank account numbers, credit card numbers, HICN) but in limited circumstances may inquire about an individual's special needs status to determine the appropriateness of enrollment in a SNP.

90 - Guidance on the Marketing Review Process

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Except where otherwise noted, all marketing materials must be reviewed prior to their use by the plan sponsor or any downstream organization that performs marketing activities on behalf of the plan sponsor. CMS's marketing review process is detailed in this section.

90.1 - Plan Sponsor Responsibilities

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

CMS reviews marketing materials to ensure that they are consistent with this chapter and are not materially inaccurate or misleading or otherwise make material misrepresentations of the plan sponsor or the products they offer. Generally, CMS does not review marketing materials for typographical or grammatical errors, unless such errors render the marketing materials inaccurate or misleading.

Prior to submitting materials as outlined below, plan sponsors are responsible for ensuring that materials are consistent with this chapter, and all other relevant CMS issued guidance and instructions. In addition, it is incumbent on the plan sponsor to create materials that provide information in a manner that is clearly stated and in no way deceptive to the recipient. (Note that not all materials are read; some are scripts.)

90.2 - Material Submission Process

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

Plan sponsors are required to submit materials for review through the Marketing Module of the HPMS. The HPMS Marketing Module is an automated tool that a plan sponsor uses to enter, track, and maintain marketing materials submitted to CMS for review and approval. HPMS has the capability to accept electronic copies of the actual marketing materials. The HPMS Marketing Module User Guide provides extensive information on how to use HPMS. However, plan sponsors must have a CMS- plan issued User ID and password with HPMS access in order to log into the system. Plan sponsors will also need to associate their User ID with the contract numbers that they you will manage in HPMS.

90.2.1 - Mandatory Use of Marketing Material Review Checklists for All Documents

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

To ensure that the materials that are submitted to CMS and ultimately viewed by Medicare beneficiaries in making their health care coverage decisions meet the requirements as outlined in these guidelines, plan sponsors must include applicable CMS model checklists (e.g., Summary of Benefits, ANOC/EOC, Provider Directory, Pharmacy Directory, Part D EOB, and transition notice) along with their submissions.

The checklist will require that a two-level review be performed by the plan sponsor prior to materials being uploaded into HPMS. Upon completion of the review, each of the two plan sponsor reviewers will attest that they have reviewed the document and that it meets the requirements as outlined by the checklist. The checklist will then accompany the material as part of the submission via a zip file.

CMS will eventually utilize a number of checklists that will correspond to all required materials. These checklists will be made available to the plan sponsor via the CMS Internet website or HPMS memorandum. In instances where a checklist does not exist for a specific marketing material, the plan sponsor will be asked to utilize a standard checklist as provided by CMS. While material-specific checklists will be tailored to the material that they represent, all checklists will contain the following:

- Relevant requirements such as proper font size;
- All mandatory disclaimers;
- A section to acknowledge that a material is model; and
- A section to cite the source for the material (for example, HPMS memo or Chapter of the Managed Care Manual or Prescription Drug Benefit Manual).

The CMS reviewer will utilize the same checklist as the basis for their review. Having both the plan sponsor and the CMS reviewer utilizing the same checklist will help to eliminate discrepancies and confusion.

90.3 - Material Disposition Definitions

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

For all marketing materials reviewed by CMS, one of the following dispositions will be rendered.

90.3.1 - Approved Disposition

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

If CMS approves a material submission, we have determined that the material submission is compliant with this chapter and any other applicable regulations, laws or relevant guidance. The material submission is approved for use in its current format and may be distributed by a plan sponsor.

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

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

90.3.2 - Disapproved Disposition

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

If CMS disapproves a material submission, we have determined that the material submission is not compliant with this chapter, applicable regulations, law or other relevant guidance.

CMS will provide a specific reason for disapproval and provide an explanation for the disapproval generated by HPMS. CMS will provide citations to the requirement with which the material was found to be non-compliant.

90.3.3 - Deemed Disposition

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262(a)(ii), 423.2262(a)(ii), 422.2266, 423.2266

If CMS does not approve or disapprove marketing materials within the specified review time frame, the following will apply:

- Materials subject to 45 day review period will be given the status of “Deemed Approved” on the 46th day.
- Materials subject to a 10 day review period will be given a status of “Deemed Approved” on the 11th day.

- Organizations that do not have a final contract will receive a conditional deemed approval. After the contract is awarded the materials disposition will be changed to “deemed approved” and can then be used.

90.3.4 - Withdrawn Disposition

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

A plan sponsor can choose to withdraw a marketing submission prior to CMS acting upon that marketing submission (e.g., beginning its review). However, plan sponsors cannot withdraw the marketing piece from HPMS; therefore, they should submit a written request to their CMS Regional Office Account Manager or marketing reviewer stating the reason(s) for the withdrawal. CMS has no regulatory authority to withdraw a marketing submission and is acting on behalf of the plan sponsor’s written request.

90.3.5 - Additional Service Area (SA)/Low Income Subsidy (LIS) Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

All plan sponsors will be allowed to submit additional service area (SA)/Low Income Subsidy (LIS) materials once the original material submission is complete. Users will be allowed to upload multiple additional SA/LIS submission files for contracts and for plan benefit packages. For example, when a plan has a service area that covers two States, one SB will be submitted as the original SB for one service area that covers one State. A plan sponsor can then submit another SB under the original SB submission which would cover the service area for the second State.

90.4 - Alternate Format

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

All sponsors will be allowed to submit Alternate Format materials once the original English version of the material submission is complete. In general, for marketing with materials that contain non-English or Braille information (in whole or in part), the plan sponsor must submit the non-English or Braille version of the marketing piece, an English translation of the piece, and a letter of attestation. Users will be allowed to upload multiple alternate format files for contracts and for plan benefit packages.

90.5 - Time Frames for Marketing Review

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262(a) 423.2262(a)

With the exception of those materials that qualify for File & Use (as outlined in §90.6), plan sponsors may not distribute or otherwise make available to eligible beneficiaries any marketing materials unless such materials have been submitted to CMS and rendered a status of approved or deemed. The marketing review time period begins the date on which the initial marketing materials are entered into HPMS.

90.5.1 - 45-Day Standard Review Period

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262(a)(i), 423.2262(a)(i)

The default review period for materials is referred to as a standard review. A standard review provides CMS 45 calendar days in which to render a review decision. If, on the 46th day, a decision has not been rendered by CMS the material will be considered “deemed approved”.

The 45 day review period applies each time an individual marketing material is submitted to CMS for review. For example, if a material is submitted to CMS for review and on the 32nd day CMS renders the decision of disapproved, upon correcting the material’s deficiencies and resubmitting the piece, the 45 day clock starts anew.

The 45 day standard review applies to materials submitted where:

- No standardized or model language is available
- Model language is available and the plan sponsor has chosen to make modifications to the model language.

90.5.2 - 10-Day Model Review Period

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262(a)(i), 423.2262(a)(i)

When a plan sponsor follows CMS model language without modification, CMS must render a decision within 10 calendar days. If, on the 11th day, a decision has not been rendered by CMS the material will be considered “deemed approved.” As with the standard review period, when a material is resubmitted for a 10 day review, CMS is provided with a fresh 10 day review period to render its decision.

The 10 day review period only applies when the plan sponsor has followed the CMS model without modification. “Without modification” means the plan sponsor used CMS model language verbatim except where indicated and allowed by CMS (for example variable fields).

(**NOTE:** The “without modification” exception will be allowed for grammatical errors only). It also means that the plan sponsor has followed the same sequence as provided in the model. See §90.7.3 for additional information on model materials.

Plan sponsors must indicate that a marketing material qualifies for model review when that material is uploaded into HPMS. This feature will only be present when a model document exists. It is likewise incumbent on the plan to ensure that any model that has been modified in any way is not submitted for a model review. Materials that are found to be non-model yet are uploaded for model review will be disapproved. A continued submission of non-model materials as model will be viewed as a compliance issue.

90.6 - File & Use Program Overview

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262(b), 423.2262(b)

Materials that qualify under the File & Use process can be distributed five calendar days after submission to CMS, but no earlier than any date established by CMS for use of specific document/materials. All plan sponsors can use the File & Use process for selected marketing materials as defined by CMS. Plan sponsors using the File & Use process must submit File & Use eligible marketing materials to CMS 5 calendar days prior to distribution and certify that the materials comply with this chapter.

90.6.1 - Materials Qualified for the File & Use Submission

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262(b), 423.2262(b)

The materials that are qualified for the File & Use process are general advertising materials, the provider directory (including combined provider directory and model directory), the combined ANOC/EOC, as well as the following model marketing documents, if used without modification:

- Pharmacy directories;
- Formularies,
- Certain CMS enrollment/disenrollment letters, and
- Certain claims, grievance, organization/coverage determinations, (including exceptions) and appeals model letters.

The HPMS Marketing Module identifies those materials that qualify for File & Use.

90.6.2 - Materials Not Qualified for File & Use Submission

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262(b), 423.2262(b)

Materials that are not qualified for File & Use are those that pose greater risk to a Medicare beneficiary if they are inaccurate in any way. These documents are:

- Summary of Benefits;
- Member Handbook;
- Member ID card;
- Mid-year Benefit Enhancement Notice;
- Enrollment forms, and
- Disenrollment forms.

In addition, explanatory marketing materials as defined in §50.5.3, unless expressly identified by CMS as qualified for the File & Use processes, must be submitted for a 45/10 day review process.

90.6.3 - Restriction on the Manual Review of File & Use Eligible Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262(b), 423.2262(b)

Plan sponsors that choose to utilize File & Use should submit at least 90 percent of materials that qualify for File & Use under this process. Plan sponsors choosing to utilize File & Use should request a manual review of no more than 10 percent of materials that qualify for File & Use.

If CMS determines that a sponsor sends a significant portion (10 percent or more) of these File & Use eligible materials through the normal 45 day review process, CMS will more closely scrutinize that sponsor's material, because CMS will interpret the sponsor's actions as demonstrating a low level of confidence in its ability to comply with the guidelines. Moreover, if, as a result of a retrospective or targeted review, CMS identifies materials that do not meet the marketing guidelines, the sponsor may face compliance actions.

90.6.4 - Loss of File & Use Certification Privileges

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262(b), 423.2262(b)

A plan sponsor may lose File & Use Certification status if it:

- Uses materials that do not meet the requirements of this chapter, or
- Fails to file two or more materials at least 5 calendar days prior to distribution or publication

NOTE: If CMS determines that a plan sponsor sends a significant portion ten (10) percent or more) of these materials through the normal, 45 day review process, CMS will more closely scrutinize that sponsor's material, because CMS will interpret the sponsor's actions as demonstrating a low level of confidence in its ability to comply with our guidelines. If this targeted review identifies materials that do not meet the requirements of this chapter, the sponsor may lose File & Use certification status. If CMS determines that a plan sponsor is non-compliant with the guidance on File & Use privileges, CMS reserves the right to take compliance actions as deemed necessary.

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

Certification Procedures (PDP Sponsors Only)

Unless the PDP sponsor requests a waiver from the File & Use Certification process, all PDP sponsors must submit File & Use Certification marketing materials to CMS 5 calendar days prior to distribution and certify that the materials comply with this chapter. It is important to note that CMS will verify that the marketing materials submitted by the organization qualify for the File & Use Certification process.

The PDP sponsor may submit File & Use Certification materials prior to executing a contract with CMS. The CMS contract will contain a provision by which the PDP sponsor 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 requirements. Thus, by executing the CMS contract, the appropriate officer of the PDP sponsor is attesting to his/her PDP's compliance with the File & Use Certification requirements.

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

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

Each plan sponsor should submit the File & Use Certification marketing materials to CMS at least 5 calendar days prior to distribution and certify by the plan sponsor's CEO/CFO or designee that the materials are in compliance with CMS requirements. As each item of marketing material is submitted, each plan sponsor is responsible for ensuring the accuracy and completeness of its marketing materials and adhering to CMS requirements. All certification forms must be sent to CMS (See Model File & Use Certification form). The requirement for submission of a signed certification form is one time only and is effective until further notice. A completed and signed Certification form must be received from the plan sponsor before it may submit File & Use Certification materials. The plan sponsor should mail the signed Certification to their appropriate CMS Regional Office.

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

Plan sponsors remain legally responsible for compliance with the marketing requirements. (See 42 CFR 422.80 and 42 CFR 422.111 for MA plans, and 42 CFR 417.427 and 42 CFR 417.428 for cost based plans). These new requirements do not modify the organizations' legal responsibility in any way. The File & Use Certification form (see Appendix 4) states that the plan sponsor agrees that all advertising materials and model documents that are used are accurate, truthful and not misleading.

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

90.7 - Additional Guidance for CMS Provided Language/Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

The following sections address CMS requirements when CMS issues documents and/or language to be used as instructed.

90.7.1 - Standardized Language

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

“Standardized language” refers to language and format developed by CMS or other Federal agencies (e.g., Office of Budget and Management (OMB) forms), which is mandatory for use by plan sponsors and cannot be modified. If modifications are allowed for standardized language those modifications must be specified in the instructions for the specific form.

90.7.2 - Standardized Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

“Standardized materials” are those model documents that a plan must utilize as provided by CMS. In these instances, plan sponsors cannot simply choose to modify the model and submit it for a standard 45-day review. The plan logo is permitted on the standardized documents.

90.7.3 - Model Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

For certain materials, CMS will provide model documents that may be used by the plan sponsor. The use of CMS model documents is optional unless specified otherwise by CMS. When a plan sponsor chooses to use a CMS model document, in order to be eligible for the 10 day marketing review period, it must do so without modification of the provided text and its order, with the exception of CMS provided variable fields, additional legal disclaimers (provided they don't conflict with the model message), the correction of grammatical errors and the addition of the company name or logo. Note that if a plan sponsor makes any other changes to a model document, however inconsequential, the material will be subject to the standard forty-five (45) day review process.

As noted in §90.5.2, and unless specified otherwise by CMS, the submission of model documents results in a 10 day marketing review period. There are, however, limited instances when CMS allows for model marketing materials to be submitted as File & Use. These will be designated as such by CMS and via the category of material within HPMS. As previously mentioned, materials that are found to be non-model yet are uploaded for model review will be disapproved. A continued submission of non-model materials as model will be viewed as a compliance issue.

When submitting a model document and in order to expedite the process, in the material description section of HPMS, a plan sponsor states which model it is using and where it can be found. (Example: Exhibit 2, PDP Model Notice to Acknowledge Receipt of Completed Enrollment, Chapter 12 of the Prescription Drug Benefit Manual.) Since there are several different models in several different Chapters, this will assist CMS in reviewing the most current model letters that plan sponsors are submitting. If the document is an attachment to a CMS issued memorandum, the plan sponsor should indicate in the material description the subject of the memo, the name of the piece and the date CMS issued the memorandum.

90.8 - Template Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

A “template material” is any marketing material that includes placeholders for variable data to be populated at a later time by the plan sponsor. Variable elements can be specific to one plan or can apply to multiple plans within the same plan sponsor that utilize the same base materials. Utilizing template materials allows a plan sponsor to submit one “master document” rather than having to submit a new document every time the variable data is changed. Examples of variable elements include date and location information for sales presentations, benefits that may vary between plans, cost sharing, premium and MAO names.

90.8.1 - Submission of Template Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

When template materials are uploaded into HPMS, they must show how the placeholders will be populated by inserting the name of the field within greater than and less than signs (e.g., <date>), or populate the placeholder fields with all variables within greater than and less than signs (e.g., <\$10.00 Copay/\$15.00 Copay>). Template materials will have only one marketing identification number regardless of the number and combination of variable elements. Changes to non-variable text in the template must be submitted for review and approved by CMS.

90.9 - Expedited Review Process for Template Annual Renewal Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

CMS has created the expedited review process to ensure that plan sponsors are able to submit information efficiently, with minimal burden, and to ensure that beneficiaries have the most complete, accurate, and timely information to make decisions during the annual election period.

While all plan sponsors may participate in the expedited procedures, we especially encourage large plan sponsors offering multiple plans to use these procedures. Use of this procedure will significantly reduce the time for CMS review and allow plan sponsors the opportunity to provide beneficiaries with important information sooner.

While plan sponsors may continue to submit materials under the standard and model review process, opting for expedited review allows plan sponsors to submit template materials without cost sharing information for review and approval by the regional office. The plan sponsor will be responsible for populating the appropriate cost-sharing and benefit information once the bid is

approved. These populated materials will not need to be resubmitted to the appropriate CMS Regional Office (RO) for additional approval prior to use, but plan sponsors must submit each variation of the template to the RO through HPMS as File & Use within 30 days of populating the materials. If any changes or corrections to the bid occur after the template is approved, the plan sponsor is responsible for correcting all marketing materials to reflect the changes.

The following documents qualify for an expedited review:

- Summary of Benefits (SB);
- Provider and/or pharmacy directories; and
- The cover letter included with the pre-enrollment marketing package

90.9.1 - Eligibility for Participation in the Expedited Process

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

All plan sponsors may submit information under the expedited process.

90.9.2 - Submission of Templates under the Expedited Review Process

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

As outlined in §90.9, template materials submitted for an expedited review must show how the placeholders will be populated and the marketing identification number regardless of the number and combination of variable elements. Templates or models submitted for expedited review must be uploaded to CMS through the HPMS marketing module. CMS will review the templates and will render a review decision within 10 or 45 days depending on the material's type and whether the plan sponsor has submitted model or non-model language. If the plan sponsor chooses to submit a SB for review without Section 3 and no hard copy changes, it will be treated as a standardized document and reviewed using the ten (10) day time frame. Model documents used as templates may not be modified.

Changes to the text in the templates once approved will require additional submission, review, and approval by CMS. Changes to placeholders populated by date or location, phone numbers, addresses, and other non-benefit or non-premium information are not required to be submitted as new material. Likewise, co-branding information added to previously approved template materials is not subject to an additional review, as long as the changes are limited to populating existing variable fields (e.g., organization name, logos or contact information).

After the bid is approved, each plan sponsor must populate the templates initially submitted with information from the bid. The material need not be approved again by CMS prior to use, but plan

sponsors must submit the materials through HPMS as File & Use within 30 days of populating the materials with bid information.

If the bid is revised at any point, the plan sponsor is responsible for correcting all marketing materials to reflect these bid changes. Any plan sponsor that uses marketing materials containing errors (for example, the benefit or cost-sharing information differs from that in the approved bid) will be required to correct those materials for prospective members and send errata sheets/addenda/reprints to current members by a reasonable time frame. In cases where non-compliance is discovered, the plan sponsor may be subject to penalties including intermediate sanctions and civil money penalties.

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

90.10 - Submission of Non-English (*Alternate Formats) Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264 (e), 423.2264(e)

CMS requires that plan sponsors should make marketing materials available in any language that is the primary language of more than ten percent of a plan's PBP service area. In addition, basic enrollee information (e.g., Summary of Benefits, etc.) must be made available to the visually impaired.

“*Alternate Formats” materials must be based on previously approved English versions of the same material. As such, the plan must submit an English version for approval first.

Upon approval of the English version, the plan sponsor must submit the following:

- The non-English version of the marketing piece (**NOTE:** “*Alternate Formats” materials that cannot be submitted via HPMS, i.e., Braille, should be kept on file at the plan).
- A letter of attestation that must be signed and certified by an authorized official employed by the plan sponsor, and must attest that the translation conveys the same information and level of detail as the corresponding English version.

Plan sponsors that submit Non-English (*Alternate Formats) materials must designate the material as “*Alternate Formats” in the HPMS using the following process during data entry:

1. The material must be given a unique Material ID;
2. The user shall select YES in the “*Alternate Formats” field;
3. Upon selecting YES in the “*Alternate Formats” field, the user will be required to enter the Material ID of the original English version in the “*Alternate Formats Original Material ID:”

field. (**NOTE:** this field will only display if the “*Alternate Formats” field has YES selected.); and

4. The submitted “*Alternate Formats” material will receive a Material Status of “Alternate Formats”.

The designation of “*Alternate Formats” will inform the Regional Office reviewer that there are non-English versions submitted.

If the plan sponsor decides to submit additional “*Alternate Formats” materials with their attestations at a later date, they may use the same process described above, for each new material, as needed.

Please note that any changes or revisions that are made to the English version should be accurately reflected in non-English materials and re-uploaded as required.

All plan sponsors will be subject to verification monitoring review and associated penalties for violation of CMS policy. In addition to verifying the accuracy of non-English marketing materials through monitoring review, CMS will also periodically conduct marketing review of non-English materials on an “as needed” basis. If materials are found to be inaccurate or do not convey the same information as the English version, plan sponsors may not continue to distribute materials until revised materials have been approved.

90.11 - Acceptable Formats

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

Plan sponsors must use the HPMS to enter all pertinent information related to a material submission and attach the material in electronic format to this entry. When submitting material, include within the comments field on the Marketing Materials Transmittal screen, the plan number and PBP for which materials are being submitted. The following are acceptable electronic formats for submitting these materials:

- Zip Files (.ZIP);
- Portable Document Format (.PDF);
- Microsoft Word (.DOC/DOCX);
- Joint Photographic Experts Group (.JPG);
- Microsoft Excel (.XLS/ .XLSX);
- DOS Text (.TXT);
- Graphics Interchange Format (.GIF); and

- WordPerfect (.WPD).

Other formats may be acceptable but must be agreed upon by the plan sponsor's Account Manager prior to making the submission.

90.12 - Submissions Outside of HPMS

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

Under extraordinary circumstances, and with prior concurrence of CMS, marketing materials may be submitted directly to CMS by mail, express mail, fax, or some other method. Please note that if materials are submitted to CMS outside of HPMS the review period begins when CMS is in possession of the materials.

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

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

Joint Enterprises are expected to:

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

Marketing materials for the Joint Enterprise may only be distributed where one or more of the contracted plan sponsors creating the single entity is licensed by that State as a risk-bearing entity or qualifies for a waiver under 42 CFR 423.410 or 42 CFR 422.372. All marketing materials must be submitted under the Joint Enterprise's contract number and must follow the CMS requirements.

90.14 - Multi-Contract Entities (MCEs)

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

If a plan sponsor operates in the jurisdiction of more than one of the CMS Regional Office, marketing materials should be submitted to the appropriate reviewer in the lead region (i.e., the region where the plan sponsor's Account Manager is located). Multi-Regional plan sponsors that submit template materials are not required to send approved copies of the template to local

regions, since this information is already available within the Health Plan Management System (HPMS).

90.15 - Review of Materials in the Marketplace

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2268, 423.2268

To ensure compliance with this chapter, CMS periodically conducts reviews of plan sponsor materials. Reviews could include, but are not limited to, the following activities:

- Review of on-site marketing facilities, products and activities during regularly scheduled contract compliance monitoring visits;
- Random review of actual marketing pieces as they are used in/by the media;
- “For-cause” review of materials and activities when complaints are made by any source, and CMS determines if it is appropriate to investigate; and
- “Secret shopper” activities where CMS requests plan sponsor materials such as enrollment packets.

If a plan sponsor’s materials are found to be non-compliant, CMS may require the plan sponsor to prepare an addendum or reissue the materials at no expense to the Government.

90.16 - File & Use Retrospective Monitoring Reviews

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262(b), 422.2264, 423.2262(b), 422.2264

CMS will conduct retrospective reviews of materials that were submitted under File & Use to ensure compliance by those plans that utilize this feature. Failing to abide by the File & Use Certification requirements may result in corrective action against the plan sponsor to protect the interest of Medicare enrollees. Plan sponsors submitting marketing materials under the File & Use Certification process through HPMS will be reminded, on an ongoing basis, of their responsibility to adhere to CMS requirements and to submit an electronic attestation at the time of material submission.

90.16.1 - Template Materials Quality Review and Reporting of Errors

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

CMS may also conduct retrospective reviews, quality checks, or audits of populated templates. CMS also expects that plan sponsors will perform quality reviews and testing as necessary to ensure that the means of populating and distributing templates with information from the approved bid is accurate. When errors are discovered, a plan sponsor must report them to their Account Manager. In addition, plan sponsors may be required to remedy the error by providing beneficiaries with updated information via errata sheets or addenda. Note that any materials, such as errata sheet or addenda, must be reviewed and approved by CMS prior to their use.

90.17 - Specific Guidance on the Submission of Websites for Review

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

Given that Internet use has increased among Medicare beneficiaries as a vehicle for accessing information, it is vital that information provided online allows beneficiaries to make an informed decision about their medical and prescription drug coverage. Therefore, plan sponsors must submit all MA and PDP websites for review. Plan sponsors should submit their websites via links in a Word document for a standard review through the Health Plan Management System (HPMS) under category code 4006-Internet web pages. Upon upload of materials in HPMS, plan sponsors will be required to attest that the website is compliant with the website requirements found in section 100. Plan sponsors must also submit any changes or updates to previously approved website links for CMS review.

Plan sponsors may make the website available for public use during the CMS review period; however plan sponsors must include the disclaimer “Pending CMS Approval” on their website until CMS has granted final approval. Use of the website while under CMS review applies only to the website text and not documents contained on the website (for example a plan may not post an unapproved member handbook on the website).

Renewing plan sponsors are required to have website content available to Medicare beneficiaries beginning October 1 for the next contract year. Plan sponsors must maintain current contract year content on their website at least until December 31st. In addition, each year’s content must be in a separate and distinct area on the plan sponsor’s website for ease of beneficiary navigation (for example having a splash page that allows the viewer to select information for the 2009 or 2010 plan year).

90.18 - Special Guidance on the Submission of SB and ANOC/EOC

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

HPMS now restricts multiple submissions of the SB and ANOC/EOC for the same contract number and plan ID (PBP number). This requirement was implemented to ensure that CMS has the ability to capture the final plan version of each ANOC/EOC and SB in HPMS. Therefore, if a plan sponsor attempts to upload an SB or ANOC/EOC when the same document type has been

previously submitted for review under a specific contract number and plan ID, the plan designation check boxes will be disabled. In order to submit the new replacement or additional SB or ANOC/EOC, plans must contact the Regional Office and have the previously submitted material “Disapproved” or “Withdrawn” (which results in a new review period). Plan sponsors that have multiple versions of the SB and ANOC/EOC for one plan ID may submit those versions in a Zip file.

One of the impacts of this requirement is in the submission of non-English versions of the SB and ANOC/EOC. In the past, non-English versions were submitted under separate material IDs. Plan sponsors that submit non-English versions must submit the materials under one material ID. The material should be designated as having “Alternate Formats” by choosing the “Yes” option on the “New Material” screen. After designating the plans covered by this material, the user should upload a zip file containing all versions of the SB and ANOC/EOC. The designation of “Alternate Formats” will inform the Regional Office reviewer that there are multiple documents enclosed with this material.

90.19 - Specific Guidance on the Submission of General Advertising Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

Whether a general advertising material qualifies for submission under the File & Use program is determined by the characteristics of the direct mail piece itself. Refer to the definition of direct mail in §20 for more guidance.

90.20 - Materials Not Subject To Review

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2260, 422.2262, 423.2260, 423.2262

The following items are examples of materials that are not subject to review by CMS and hence should not be uploaded into HPMS. While the materials listed below are not subject to CMS review, plan sponsors are still responsible for ensuring that all materials intended for Medicare beneficiaries meet the applicable CMS marketing standards as outlined in these guidelines. In addition, plan sponsors should have a means of tracking and maintaining such materials so as to have them available upon request by CMS.

- Privacy notices (privacy notices, however, are subject to enforcement by the Office of Civil Rights);
- Press releases;
- Certain member newsletters (newsletters are not subject to review as marketing materials unless sections are used to enroll, disenroll, and communicate with

members on product specific information (e.g., benefits or coverage), membership operational policies, rules and/or procedures);

- Blank letterhead/fax coversheet and envelopes that do not include promotional language;
- General health promotion materials that do not mention any specific plan related information. (e.g., health education and disease management materials). In general health promotion materials should meet CMS' definition of "educational;"
- Non-Medicare beneficiary-specific materials that do not involve an explanation or discussion of the Medicare Prescription Drug Benefit, Medicare Advantage or 1876 Cost plans (e.g., notice of check return for insufficient funds, letter stating Medicare ID number provided was incorrect, billing statements/invoices, marketing representative recruitment documents, premium payment coupon book);
- Sales representative recruitment and training documents;
- Customer service correspondence pertaining to unique questions or issues that affect an individual or small subset of the plan's enrollment;
- Medication Therapy Management (MTM) program material that address issues that are unique to individual members;
- Materials used in the education of beneficiaries and other interested parties. The materials must meet the definition of "educational." See §70.7 for more information on educational material;
- Coordination of Benefits Surveys;
- Mail order pharmacy election forms
- Other member surveys;
- Envelopes (unless they contain information on them that pertains to plan benefits, co-pays, or other marketing information including non-Medicare products and services); and
- VAIS (refer to §110.3 for specifics).

100 - Special Guidance on Plan Sponsor Websites

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

(Section 508 of the Rehabilitation Act (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 (P.L. 105-220), August 7, 1998)

All Plan sponsors are required to have an Internet website 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 website address: <http://www.section508.gov>.

100.1 - Plan Sponsor Website Requirements

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264(a), 423.2264(a)

All plan sponsors that offer Part D benefits must have a website or web page dedicated to each product they offer (with the exception of employer based plans see §130). This site/page must include the name of the plan sponsor and clearly indicate that it is a Medicare contractor (see §50 on Marketing Material Types and Applicable Disclaimers). All marketing materials can include a web address that connects the beneficiary either to the corporate website or directly to the organization's Medicare specific pages. Subsequently, web pages that are specifically designed for the Medicare based products should be accessed either directly from the organization's web address or from the organization's corporate website.

A plan sponsor may provide access to its organization's other lines of business on its Medicare-based website. However, to avoid beneficiary confusion, any links provided by the plan sponsor to health-related or non-health related products/services must be clearly labeled as such to allow the beneficiary to make an informed decision and understand that by clicking on those links, he/she will be leaving the Medicare-specific web pages.

Any marketing materials that a plan sponsor places on its website must be in a minimum 12 point Times New Roman-equivalent font. CMS acknowledges that the plan sponsors do 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 plan sponsor codes the font for the web page, not how it actually looks on the user's screen.

100.2 - Organization Website Content

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

Website content should use language from marketing materials that have been reviewed and approved and/or appropriately submitted to CMS under File & Use, in accordance with this chapter (e.g., advertising, Summary of Benefits, formulary, pharmacy/provider directory, and EOC). Plan sponsors may provide this information via links from 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.

Plan sponsors are required to provide certain current contract year information on a website for members and prospective enrollees. Renewing organizations are also required to provide website content beginning October 1 for the next contract year. Plan sponsors must maintain current contract year content at least until December 31 on their website. In addition, upcoming contract year content must be included in a separate and distinct area on the plan sponsor's website, when the plan sponsor begins marketing for the upcoming year. The website content for the upcoming contracting year must be submitted to CMS as described in §90.17 and Appendix 3.

To facilitate the marketing review process, plan sponsors should include the approved material ID that will be displayed on the websites, and on the transmittal form and the appropriate status. For example:

- Pharmacy Directory SXXXXX_XX – Approved.

The following information must be included on all plan sponsor websites:

- Toll-free customer service number, TTY number, physical or Post Office Box address, and hours of operation;
- Plan Description (for each product offered by the plan sponsor):
 - Service area(s);
 - 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;
- When applicable, provide the notice associated with removing a Part D drug from the Part D plan's formulary, adding prior authorization, quantity limits, step therapy or other restrictions on a drug and moving a drug to a higher cost-sharing tier. This information is to be maintained on the website until the next annual mailing of the updated formulary; and
- Process for contacting Social Security Office or Medicaid to inquire about LIS status or level.

100.2.1 - Pharmacy Access Information

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.120(a) (1), 423.128(b) (5), (7), (9)

All plan sponsors that offer Part D benefits must include the following on their website:

- Pharmacy information as defined above in §60;
- 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);
- Description of Out-of-Network coverage;
- Current formulary information (updated monthly) based on guidance provided in §60.5.4;
- An explanation of the plan's Part D grievance, coverage determination (including exceptions), and appeals processes, and the procedures plan members must follow to file a grievance or request a coverage determination (including an exception) or appeal;
- Quality assurance policies and procedures, including Medication Therapy Management (MTM), and drug and/or utilization management. Plan sponsors must identify the conditions for which MTM programs are available, inform beneficiaries that these programs may have limited eligibility criteria, make clear that these programs are not considered a benefit, and remind beneficiaries to contact the organization's customer service for additional information;
- Potential for contract termination;
- Beneficiaries' and plan's rights and responsibilities upon disenrollment;
- How to obtain an aggregate number of grievances, appeals, and exceptions filed with the plan sponsor; and
- Process for contacting Social Security Office or Medicaid to inquire about LIS status or level.

100.2.2 - Provider Access information

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.111(b) (3)

MA and Cost plans must include an electronic provider directory applicable for all products and defined by service areas or general geographic area. This may be accomplished by:

- Posting a searchable “master” provider directory that represents the aggregate network for the plan sponsor; and
- Posting individual provider directories by product and/or service area (i.e., mirroring those that will be printed for the plan sponsor’s membership).

100.2.3 - Specific Guidance Regarding Grievance, Coverage Determination (Including Exceptions) and Appeals Website Requirements

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.111(b) (8), 423.128(b) (7)

Plan sponsors must include the following specific information on the organization’s website:

- A summary of the plan sponsor’s grievance, coverage determination (including exceptions), and appeals processes;
- Instructions for requesting a coverage determination (including an exception), including:
 - The telephone number designated for receiving oral requests (plan sponsors must accept expedited requests verbally and may choose to accept standard requests verbally);
 - The mailing address and fax number designated for receiving written requests;
- Instructions for requesting a redetermination (appeal), including:
 - The telephone number designated for receiving oral requests (plan sponsors must accept expedited requests verbally and may choose to accept standard requests verbally);
 - The mailing address and fax number designated for receiving written requests;
- A link to the plan sponsor’s redetermination request form, if the plan has developed one;
- Any form developed by the plan sponsor to be used by a physician or enrollee to satisfy a prior authorization or other utilization management requirement;
- Any form developed to be used by physicians when providing a supporting statement for an exceptions request;

- Contact numbers that enrollees and physicians can use for process or status questions.
- Instructions about how to appoint a representative and a link to CMS' Appointment of Representation form (Form CMS-1696) located on CMS's Part D appeals webpage: http://www.cms.hhs.gov/MedPrescriptDrugApplGriev/13_Forms.asp ;
- A link to the plan's Evidence of Coverage (EOC) and a reference to the sections on the EOC that discuss the grievance, coverage determination (including exceptions), and appeals processes;
- A link to the Request for Medicare Prescription Drug Determination Request Form (for use by enrollees) located on CMS's Part D appeals webpage: http://www.cms.hhs.gov/PrescriptionDrugApplGriev/13_Forms.asp ; and
- A link to the Medicare Part D Coverage Determination Request Form (for use by provider) located on CMS's Part D appeals webpage: http://www.cms.hhs.gov/MedPrescriptDrugApplGriev/13_Forms.asp.

100.2.4 - Low Income Subsidy (LIS) Website Premium Summary Table for People Receiving Extra Help

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 423.128(b) (2) (ii) and (iii)

Plan sponsors must inform potential enrollees of what their plan premium will be once they are eligible and receive the LIS. Plan sponsors that do not use the model LIS Premium Summary Table must ensure that the following information is available for each plan benefit package (PBP) they offer:

- A statement indicating that the enrollee's premium will generally be lower once he/she receives extra help from Medicare;
- The four different premium amounts;
- An explanation that the premiums listed do not include any Part B premium the member may have to pay, and
- A statement indicating that the premiums listed are for both medical services and prescription drug benefits (MA-PD plans only).

NOTE: Even if plan sponsors offer a \$0 plan premium they should still include the above information on their website.

100.3 - Required Links

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.111(b) (8), 422.2264(a), 423.128(b) (7), and 423.2264(a)

The following information must be accessible via a link on the plan sponsor's website. If the specific marketing materials have not been reviewed and approved or appropriately submitted to CMS under File & Use in accordance with this chapter, an inactive link must be included on the website with a notation (e.g., coming soon):

- Summary of Benefits;
- Enrollment Instructions and Forms;
- Evidence of Coverage ;
- LIS Premium Summary Chart;
- Privacy Notice (privacy notices are subject to enforcement by the Office of Civil Rights);
- Plan Transition process information via a link from the Medicare Prescription Drug Plan Finder (<http://www.medicare.gov/MPDPF/home.asp>) to the organization's website;
- Information related to the plan's exception and appeals process, including instructions and forms required to file and complete a coverage determination (including an exception) or appeal request; and
- Provide a link on their website to the section of CMS' website regarding Best Available Evidence (BAE) policy and make information about BAE policy readily available for those who contact the plan sponsor's call center. Refer to CMS web link:
http://www.cms.hhs.gov/PrescriptionDrugCovContra/17_Best_Available_Evidence_Policy.asp

Plan sponsors should be aware that additional links to documents may be required in the future.

100.3.1 - Prohibited Links

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Federal Food Drug and Cosmetic Act

Part D plans may not provide links to foreign drug sales on their websites.

100.4 - Required Disclaimers on Websites

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

Plan sponsors must include all applicable explanatory disclaimers as referenced in §50.5.

100.5 - Enrollment via the Internet

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.60, 422.2268, 423.32, 423.2268

Plan sponsors (except for Cost Contractors) are allowed to accept enrollment requests via the organization's secure Internet website using materials and web pages that have been submitted to CMS for review and received approval. The following information applies to Internet enrollment conducted by a plan sponsor directly.

PDP organization enrollment forms and screens must follow the guidance provided in §30.1.2 of Chapter 3 of the Prescription Drug Benefit Manual. MA and MA-PD organization enrollment forms and screens must follow the guidance provided in §40.1.2 of Chapter 2 of the Medicare Managed Care Manual.

Plan sponsors are not permitted to market or enroll beneficiaries in other lines of business as part of the online enrollment process.

In developing and submitting online enrollment screens, organizations must include all elements from the applicable model enrollment form, and provide contact information for questions, including toll free telephone and TTY numbers, as well as requirements in Chapters 2 and 3 respectively of the Medicare Managed Care Manual and the Prescription Drug Benefit Manual.

Following the acceptance of an online enrollment request, the plan sponsor must have a tracking mechanism to provide the individual with evidence that the internet enrollment request was received and in addition, must:

- Offer to send an email or other confirmation to the beneficiary to denote receipt of the online enrollment request; or
- Provide a summary of the plan for which the individual has requested enrollment; or
- Provide a statement that the individual will receive a notice in the mail acknowledging receipt of the completed enrollment request or requesting additional information.

100.5.1 - Required Materials When Online Enrollment is Utilized

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.503, 423.2260

Plan sponsors that choose to allow online enrollment via their website should reference §30.8.1 and ensure that all applicable materials are posted in such a manner as to allow beneficiaries the ability to read them prior to accessing an enrollment form. Note that the plan sponsor cannot make the Medicare beneficiary read or sign off on these documents as a condition of enrollment; rather they must only make them available.

110 - Specific Guidance about Value-Added Items and Services

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Chapter 4 of the Medicare Managed Care Manual

110.1 - Definition of Value-Added Items and Services (VAIS)

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Chapter 4 of the Medicare Managed Care Manual

Value-Added Items and Services (VAIS) are non-benefit items and services provided to a plan sponsor's enrollees that meet the definition of VAIS below. VAIS may not be funded with Medicare program dollars. However, VAIS may be of value to some beneficiaries and may be commonly available to commercial enrollees.

VAIS may be offered by Medicare Advantage Organizations, Prescription Drug Plans, and by 1876 Cost Plans. An item or service is classified as a VAIS if the cost, if any, incurred to the plan sponsor in providing the item or service is solely administrative. A cost is not automatically classified as administrative simply because it is either minimal or non-medical. The cost, if any, must be intrinsically administrative: The cost must cover only such items as clerical or equipment and supplies related to communication (such as phone and postage), or database administration (such as verifying enrollment or tracking usage).

Note that this definition does not require that VAIS be health-related. A VAIS is not a benefit since no direct medical or pharmaceutical cost is incurred to the plan sponsor in providing the VAIS.

110.2 - VAIS Examples

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Chapter 4 of the Medicare Managed Care Manual

The following two examples clarify the above definition:

(1) An MA plan offers an in-network vision exam benefit (for which it incurs a direct medical cost). The MA plan also offers a 5 percent discount on a vision exam out-of-network. Enrollees are instructed to pay for the vision exam out-of-network and receive a 5 percent discount. The discount is covered by the vision exam center to broaden its market. Consequently, the MA plan does not incur a direct medical cost as a result of this discount. The MA plan may incur administrative costs related to negotiating the discount, notifying members, and verifying eligibility.

Since the plan does not incur a direct medical cost in providing the vision exam out-of-network, the discount may not be classified as a benefit. The plan may offer the discount on out-of-network vision exams as a VAIS. However, since the out-of-network vision exam is not a benefit it may not be advertised on the Medicare Options Compare site nor mentioned in the PBP. Other restrictions on advertising apply.

A similar analysis would apply if the plan offered a vision exam benefit and the Center providing the vision exam provided a 10 percent discount on glasses purchased by those enrollees obtaining vision exams. The discount on glasses is a VAIS, not a benefit; it may not be advertised on the Medicare Options Compare site nor mentioned in the PBP.

(2) An MA plan wishes to offer free groceries with vouchers to its enrollees.

Such grocery vouchers could not be offered as VAIS if the plan pays costs for the vouchers provided. The cost is not “solely administrative” since the MA plan is paying for vouchers even if the cost is minimal.

110.3 - CMS Review of VAIS Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Chapter 4 of the Medicare Managed Care Manual

Because VAIS are not benefits as described within CMS regulations, CMS will not require prior approval of materials solely describing VAIS. If the description of the VAIS is a part of a larger marketing piece, plans must submit the piece in its entirety, but should make the reviewer aware of the VAIS section. While VAIS are not typically the subject of CMS site visits, CMS reserves the option to review VAIS, either during an ordinary or special monitoring visit, especially if problems or complaints arise.

110.4 - Further Requirements on VAIS

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Chapter 4 of the Medicare Managed Care Manual

Since VAIS is not a benefit, therefore:

- VAIS may not be priced in the bid;
- VAIS is not reviewed during the annual review of plan benefit package design; and
- VAIS may not appear in the PBP, SB ANOC or EOC. Plan sponsors may include VAIS along with their ANOC, SB and/or EOC in one bound brochure as long as the VAIS are clearly distinct from the ANOC, SB or EOC (such as on a different color piece of paper), and the information on VAIS includes the following disclaimer:

“The products and services described <below/above> are neither offered nor guaranteed under our contract with the Medicare program. In addition, they are not subject to the Medicare appeals process. Any disputes regarding these products and services may be subject to the <Name of Plan> grievance process.”
The above disclaimer should be on all marketing materials if the material mentions about VAIS.

Organizations offering VAIS must:

- Offer it for the entire contract year;
- Offer it uniformly to all plan members;
- Maintain the privacy and confidentiality of enrollee records in accordance with all applicable statutes and regulations;
- Comply with all applicable HIPAA laws. For information on HIPAA see <http://www.hhs.gov/ocr/hipaa/>. In particular, a plan sponsor may not directly contact Medicare beneficiaries if a VAIS item or service is not directly health related. This prohibition of contact includes distributing names, addresses, or information about individual enrollees for commercial purposes. If the organization or sponsor uses a third party to administer VAIS that is not directly health related, the organization or sponsor is ultimately responsible for adhering to and complying with these confidentiality requirements; and
- Comply with all relevant fraud and abuse laws, including, when applicable, the Federal anti-kickback statute and civil monetary penalty prohibiting inducements to beneficiaries.

110.5 - Value Added Items and Services Provided to Employer Groups

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Chapter 4 of the Medicare Managed Care Manual

VAIS may be offered to employer groups including Employer/Union-only Group Waiver Plans (EGWPs) and employer/union sponsored enrollments into individual market Medicare plans open to general enrollment.

120 - Guidance on Marketing and Sales Oversight and Responsibilities

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2272, 422.2274, 423.2272, 423.2274

As provided in §10 marketing includes any activity of an employee of a plan sponsor, an independent agent, and independent broker or other similar managerial marketing position intended to affect a beneficiary's choice among Medicare plans. Marketing by a person who is directly employed by an organization with which a plan sponsor contracts to perform marketing or a downstream marketing contractor is considered marketing by the plan sponsor. Plan sponsors are responsible for all downstream activities made on their behalf.

A plan sponsor may not charge a beneficiary, or allow its marketing representatives to charge a beneficiary, a marketing fee outside of the approved premium, for the purpose of compensating a marketing representative. All costs associated with the marketing of a plan are the responsibility of the plan sponsor and an enrollee cannot be held responsible for the cost of marketing beyond their basic premium. Such costs are considered part of the plan sponsor's administrative costs required to be in the plan sponsor's bid.

120.1 - Compliance with State Appointment Laws

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2272(c), 423.2272 (c)

Sections at 42 CFR 422.2272(c) and 42 CFR 423.2272 (c) state that plan sponsors must comply with State appointment laws. For an agent or broker to sell Medicare products, that agent or broker must be appointed in accordance with the State appointment law and that if there are any fees required as part of the appointment law, the fees must be paid. Please note that CMS does not intend to dictate who should pay the fees.

120.2 - Plan Reporting of Terminated Agents

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2272(d), 423.2272(d)

Sections at 42 CFR 422.2272(d) and 42 CFR 423.2272(d) require that plan sponsors report the termination of any brokers or agents, and the reasons for the termination, to the State in which the broker or agent has been appointed in accordance with the State appointment law. Plan sponsors should make the report available upon CMS' request until further guidance has been issued regarding designated reporting dates to CMS.

120.3 - Agent/Broker Training and Testing

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2274(b)(c), 423.2274(b)(c)

Plan sponsors must ensure annually that brokers and agents selling Medicare products are trained on Medicare rules and regulations and on details specific to the plan products being sold by the brokers and agents. Consistent with 42 CFR 422.2274(b) and (c) and 42 CFR 423.2274(b) and (c) plan sponsors must also ensure that brokers and agents selling Medicare products are trained and tested annually on their knowledge of Medicare rules and regulations, as well as on details of the plan products being sold. To the extent that CMS provides training and testing for agents and brokers, CMS certification will not confer any special advantage to the agents and brokers who participate. Agent and broker use of this certification as a marketing tool will be prohibited.

In order to sell Medicare products, a broker or agent should receive a passing score of at least 85 percent on the test. Tests may be in the form of a written test or computerized. Plan sponsors must ensure that their training and testing programs are designed and implemented in a way that the integrity of the training and testing is maintained. In doing so, they must have a process for handling instances in which agents do not pass the test on the first try. Plan sponsors should document that each agent/broker has been trained and have the ability to provide this information to CMS upon request.

120.4 - Agent/Broker Use of Marketing Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2262, 423.2262

Plan sponsors are responsible for all marketing materials used by their subcontractors in this chapter to market their plan. All marketing materials, as defined, and used by plan sponsors or their subcontractors must be submitted by the plan sponsor to CMS for review and approval prior to use. Marketing materials cannot be submitted directly by a third party to CMS.

Agents and/or brokers are permitted to create and distribute materials, such as a business card or a letter, indicating the products (for example HMO, PPO, or PDP) that he/she is selling for a specific plan or plan(s). Such materials cannot be used to market, per CMS' definition, the products the sales person is selling. This limited flexibility is intended to allow those who sell MA plans or PDPs the ability to convey this fact without the need for the plan to submit each piece to CMS for review. It is imperative that any broker-created materials not contain any component of "marketing" as defined in §20. Anything beyond this strict allowance must be submitted via the plan sponsor for CMS review and approval. Please note that this guidance in no way precludes any more stringent rules or contractual obligations that a plan sponsor may have in place to further restrict broker communication.

Additionally, agent/brokers who wish to use materials containing plan information from multiple plan sponsors can either have one plan sponsor submit the material on behalf of all the other

organizations, or have the piece submitted and approved by CMS for each plan sponsor mentioned prior to use.

120.5 - Agent/Broker Compensation

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2274(a), 423.2274(a)

Sections at 42 CFR 422.2274(a) and 42 CFR 423.2274(a) set forth limits on agent and broker compensation. These limits are intended to ensure that compensation does not create incentives for agents and brokers to assist beneficiaries with plan selection using criteria, other than the beneficiaries' health care needs and preferences. These limits apply to MA organizations and Part D sponsors that market through independent brokers or agents. These compensation rules are designed to eliminate inappropriate moves of beneficiaries from plan-to-plan.

Plan sponsors are not required to compensate agents or brokers for selling Medicare products. However, when they do elect to compensate, plan sponsors must impose requirements designed to ensure that agents or brokers enroll beneficiaries based on the plan that best meets their health care needs. A beneficiary in a new plan should not be enrolled based on the agent's or broker's financial interests but rather the beneficiary's health care needs.

120.5.1 - Definition of Compensation

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2274(a), 423.2274(a)

For purposes of this chapter, "compensation" includes pecuniary or non-pecuniary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes, awards, and finder's fees.

Compensation **DOES NOT** include the following:

- The payment of fees to comply with State appointment laws;
- Training;
- Certification;
- Testing costs;
- Reimbursement for mileage to, and from, appointments; and
- Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials

120.5.2 - Compensation Types

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2274(a) (3), 423.2274(a) (3)

The regulations provide for two types of compensation: initial compensation and renewal compensation.

Renewal compensation is equal to 50 percent of the initial compensation amount and is paid in the years a beneficiary's initial year of enrollment in a plan. It is also paid when a beneficiary enrolls in a different plan of "like plan type" following the initial year of enrollment.

NOTE: Renewal compensation will apply whether or not the new enrollment is in the same or a new (receiving) organization (e.g., the member moves to a different plan within the same parent organization).

A "like plan type" refers to moves from:

- A PDP to another PDP, and
- An MA or MA-PD to another MA or MA-PD, or

Initial compensation is paid for new enrollments into MA plans or PDPs, and enrollments into different plan types. By different plan types, we mean enrollments from:

- An MA or MA-PD to a PDP;
- A PDP to an MA or MA-PD, or
- A Cost plan to an MA or MA-PD or PDP.

NOTE: For dual enrollments (e.g., in an MA-only plan and a standalone PDP), the compensation rules apply independently to each plan. However, when dual enrollments are replaced by an enrollment in a single plan, compensation is paid based on the MA movement (e.g., movement from an MA-only and PDP to an MA-PD would be compensated at the initial compensation amount for the MA to MA-PD "like plan type" move.)

120.5.3 - Compensation Cycle (6-Year Cycle)

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2274(a), 423.2274(a)

The regulations provide that, after a beneficiary is enrolled in an MA plan or PDP by an agent or broker, a renewal compensation would be paid for five years after the initial compensation year;

creating a 6 year compensation cycle. However, if an enrollee moves to a plan of a different plan type, the agent or broker may receive compensation at the initial rate and the 6 year cycle starts over again. Once the compensation cycle expires, it does not restart until the beneficiary enrolls into another plan. CMS will provide a monthly report that will identify beneficiary enrollment changes and the corresponding compensation cycle status update.

120.5.4 - Specific Guidance for Developing and Implementing Compensation Strategy

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2274(a), 423.2274(a)

- CMS defines "year" as a plan year, January 1 through December 31.
- For the purpose of calculating compensation, the movement by a beneficiary from an employer group plan to an individual plan (either within the same plan sponsor or between different plan sponsors) counts as an initial enrollment.
- Plan sponsors should pay compensation in accordance with the structure in place when the enrollment occurred so long as the agent is in good standing and the member is still enrolled. Further, the commission structure of the receiving health plan (rather than the losing health plan) applies to any replacement enrollment. An agent is in good standing if (s)he is appointed to sell in the State (if required), annually trained and tested, and maintains a passing score of 85 percent.
- CMS does not differentiate between agents, brokers, general agents, general agencies, and distribution partners. It is the plan sponsor's responsibility to ensure that all of its contracted sales staff's compensation levels abide by CMS rules.
- CMS compensation requirements do not apply to employed agents.
- If a contracted agent receives a base salary and sells exclusively for one plan sponsor, that agent may be considered employed for purposes of applying CMS agent/broker compensation requirements.
- While CMS does not dictate how plans should pay compensation, (e.g., monthly, quarterly, annually), CMS prohibit plans from paying compensation in advance (e.g., paying 5 years' residuals up front).
- Referral fees are equivalent to finder's fees and governed by CMS regulations.
- Bonuses (announced or unannounced prior to payment) must be calculated into the compensation structure and fall within CMS rules. A bonus does not fall outside CMS rules because it was not announced to agents or brokers in advance.

- Compensation for dual enrollments should be paid independently (e.g., when a beneficiary enrolls in both a Cost plan and a standalone PDP, compensation should be paid for both enrollments.)
- When a beneficiary enrolls in an MA-PD plan, compensation should be paid using the MA compensation amount. Plans sponsors should not pay both the MA and PDP compensation amounts.

120.5.5 - Compensation Calculation

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2274(a), 423.2274(a)

The aggregate (commissions, bonuses, etc.) of the compensation amount paid for selling or servicing an enrollee during each of the 5 individual renewal years of a 6 year cycle must be fair-market value for the work performed and no more, and no less, than 50 percent of the aggregate (commissions, bonuses, etc.) of the compensation amount paid for that beneficiary in the initial year of the 6 year cycle required under 42 CFR 422.2274(a)(1)(iii) and 42 CFR 423.2274(a)(1)(3). In addition, all parties should be mindful that their compensation arrangements including arrangements with Field Marketing Organizations (FMOs) and other similar type entities must comply with fraud and abuse laws, including the Federal anti-kickback statute.

120.5. 6 - Specific Guidance for Recovering Compensation Payments (Charge-Backs)

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2274, 423.2274

Plans are required to recover compensation payments from agents under two circumstances: 1) when a beneficiary disenrolls from a plan within the first three months of enrollment (rapid disenrollment) and 2) any other time a beneficiary is not enrolled in a plan.

Example 1 – A beneficiary enrolls in Plan G effective in March. In July the beneficiary decides to enroll in Plan T with an effective date of November 1st. If plan G has paid the agent for March through December, then it must recover compensation from the agent for November and December.

Example 2 – A beneficiary enrolls in Plan D with an effective date of February 1. In April, the beneficiary disenrolls. Since the beneficiary rapidly disenrolled, Plan D must recover all compensation paid for that enrollment.

Example 3 – An agent enrolls a beneficiary into Plan K with an effective date of January 1st. The beneficiary is subsequently disenrolled because the plan was not able to verify

eligibility information. In March, the plan receives the necessary information to verify the enrollment. The beneficiary is re-enrolled in the plan. The plan must pay the agent for the entire time the beneficiary is enrolled in the plan (including when enrollment is retroactive).

Example 4 – A beneficiary enrolls into Plan A with an effective date of January 1. In May, the beneficiary enrolls into Plan B. In October, the beneficiary decides to change plans again. This time the beneficiary enrolls into Plan Z. Plan A is responsible for paying the agent through April. Plan A must recover any payments made that cover May through December. Plan B is responsible for paying compensation for May through September. Plan B should not have paid anything to the agent for January through April because Plan A was responsible for those payments. Additionally, Plan B is responsible for recovering any payments covering October through December. Finally, Plan Z is responsible for paying the agent from October through December. Plan Z should not have paid anything to the agent for January through September.

120.5.7 - Guidance for the 2010 Plan Year and Beyond

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2274, 423.2274

For 2010 and subsequent years, the compensation amount paid to an agent or broker for enrollment of a Medicare beneficiary into a plan sponsor's plan is as follows:

- For an initial enrollment, the prior year's initial compensation adjusted by the change in rates that CMS announces each year; and
- For renewals, an amount equal to 50 percent of the initial compensation. The broker or agent is paid a renewal compensation for each of the next (5 years the enrollee remains in the plan in an amount equal to 50 percent of the initial year compensation amount (creating a 6 year compensation cycle).

120.5.8 - Third Party Marketing Entities

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2274(a), 423.2274(a)

If the plan sponsor contracts with a third party entity such as a FMO or similar type of entity to sell its insurance products or perform services (for example, training, customer service, or agent recruitment), the amount paid to the third party must be fair-market value and must not exceed an amount that is commensurate with the amounts paid by the plan sponsor to a third party for similar services during each of the previous 2 years.

120.6 - Activities That Do Not Require the Use of State-Licensed Marketing Representatives

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2274(c), 423.2274(c)

There are plan activities, typically carried out by the plan sponsor's customer service department, that do not require the use of State-licensed marketing representatives. These include the following:

- Providing factual information;
- Fulfilling a request for materials; and
- Taking demographic information in order to complete an enrollment application at the initiative of the enrollee.

These examples are legitimate customer service activities that would not require using State-licensed marketing representatives. A State-licensed representative is required when there is a marketing activity involved as defined in §20

To further clarify, when employee customer service representatives, employed or contracted agents, and/or external agents and brokers perform customer service functions, such as answering questions and/or accepting enrollments on behalf of enrollees who have already decided to enroll in a particular plan offered by the plan sponsor, these functions are considered legitimate customer service representative activities and do not trigger the need to use a State-licensed marketing representative. All required CMS enrollment procedures and guidance apply.

130 - Guidelines Applicable to Employer/Union Group Health Plans

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

1857(i), 1860D-22(b), 42 CFR 422.2276, 423.2276

As provided in §10.1 of Chapter 9 of the Medicare Managed Care Manual and §10.1 of Chapter 12 of the Prescription Drug Benefit Manual, CMS has authority under Sections 1857(i) and 1860D-22(b) of the Social Security Act to waive or modify requirements that hinder the design of, the offering of, or the enrollment in employment-based Medicare plans offered by employers and unions to their members. Waivers and modifications may be granted to plan sponsors offering "individual" PDPs or MA plans, or plan sponsors offering customized employer group PDPs or MA plans offered exclusively to employer/union group health plan sponsors (known as employer/union-only group waiver plans, or EGWPs). CMS has issued various employer group waivers and/or modifications to the Medicare Part C and Part D rules for marketing and disclosure/dissemination of information to Medicare beneficiaries. For specific guidance regarding these waivers or modifications of marketing and disclosure/dissemination of

information requirements for employer/union-sponsored group health plans, please refer to §20.3 of Chapter 9 of the Medicare Managed Care Manual, and §20.3 of Chapter 12 of the Prescription Drug Benefit Manual.

Beginning with contract year 2009, plan sponsors offering employer group health plans are no longer required to submit informational copies of their dissemination materials to CMS at the time of use. However, as a condition of CMS providing these particular waivers or modifications, CMS reserves the right to request and review these materials in the event of beneficiary complaints or for any other reason it determines to ensure the information accurately and adequately informs Medicare beneficiaries about their rights and obligations under the plan. For more information about these requirements, refer to §20.3.2.1.1 of Chapter 9 of the Medicare Managed Care Manual, and §20.3.2.1.1 of Chapter 12 of the Prescription Drug Benefit Manual.

In addition to the guidance specific to marketing materials, much of the procedural guidance as outlined in this chapter is also applicable to employer plans. Please reference the grid below for further guidance on the applicability of the various requirements.

Table - 130-1. Marketing Provisions – Employer/Union Group Plans

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Marketing Provisions that apply to Employer/Union Group Plans (these requirements are applicable for the transaction between the agent/broker selling the plan to the employer/union. All activities conducted by the employer/union or its designees to sign up individual employees to the plan(s) selected by the employer/union are excluded from these provisions.)		
Provision	Yes	No
Nominal Gifts	X	
Unsolicited Contacts		X
Cross-selling		X
Scope of Appointments		X
Sales/Marketing in Health Care Settings	X	
Sales/Marketing at Educational Events	X	
Co-branding	X	
Provision of Meals		X
Appointment of Agents/Brokers	X	
State Licensed	X	
Reporting of Terminated	X	

Agents/Brokers		
Agent/Broker Compensation		X
Agent/Broker Training and Testing – Agents must be thoroughly familiar with the products they are selling; including the plan specific details and the Medicare rules that apply to the specific products. The organization/sponsor is responsible for ensuring that the agents selling for them have sufficient knowledge.	X (training)	X (testing)

140 - Special Guidance for Medicare Medical Savings Account (MSA) Plans

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

MSAs are required to abide by all applicable guidance set forth in this chapter.

140.1 - General Advertising Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

General advertisement materials, as defined by these guidelines, created to promote MSAs must adhere to all applicable guidance in §50. In addition, due to the unique nature of MSAs, MSA plan marketing materials should:

- Include the standard definition of an MSA:

“MSA Plans combine a high deductible Medicare Advantage Plan and a bank account. The plan deposits money from Medicare into the account. You can use the money in this account to pay for your health care costs, but only Medicare-covered expenses count toward your deductible. The amount deposited is usually less than your deductible amount, so you generally will have to pay out-of-pocket before your coverage begins.”

- Display “(MSA)” or “(Medical Savings Account)” in all headers of all marketing displays;

- Include the member’s obligation to continue to pay Medicare Part B premiums, as well as the fact that there are no plan premiums;
- Not imply that an MSA plan functions as a supplement to Medicare;
- Not use the term “network” to describe a list of contracted preferred providers, if available;
- Include the following statement:

“Medicare MSA Plans don’t cover prescription drugs. If you join a Medicare MSA Plan, you can also join a Medicare Prescription Drug Plan to get drug coverage.”

NOTE: MSAs cannot offer Part D but enrollees can enroll in a separate PDP plan. MSAs should reference all of the MA and PDP plan sponsors’ offerings, and not just the MSA plan so the beneficiary knows that he/she can choose any PDP and is not restricted to the MSA plan sponsor’s own PDP offering. (42 CFR 422.4(c)(2)); and

- Provide specific information to beneficiaries related to all aspects of the MSA plan’s cost-sharing, especially what is and is not counted towards the deductible, and how the MSA accounts are invested, the nature of the risk associated with the accounts, and the record of return on investments over the last 2 years.

140.2 - Explanatory Marketing Materials Requirements

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2264, 423.2264

Explanatory marketing materials, as defined in this chapter, created to promote MSAs must adhere to all applicable guidance found in §50.4. In addition, due to the unique nature of MSAs, plan sponsors must also include the following information in explanatory marketing materials for MSA plans.

- Explain that Medicare beneficiaries are not eligible for an MSA plan if they:
 - Have health coverage that would cover Medicare MSA plan deductibles, including benefits under an employer or union group health plan. (42 CFR 422.56(d));
 - Are eligible for health care benefits through the Department of Defense (TRICARE) or the Department of Veteran Affairs (VA). (42 CFR 422.56(b));

- Are enrolled in a Federal Employees Health Benefits Program (FEHBP). (42 CFR § 422.56(b));
- Are eligible for Medicaid. (42 CFR § 422.56(c));
- Have end stage renal disease (permanent kidney failure requiring dialysis or a kidney transplant).
- Are currently getting hospice care; and
- Live outside of the US more than 183 days a year. (42 CFR 422.56(a)).

Explain the unique features of MSA plans, including the MSA trustee arrangement, costs to the member before and after the deductible is met, what costs count towards the deductible, how they are tracked by the plan and what happens to the money in the account if the member leaves the plan.

- Include the following statements:

“Enrollment is generally for the full calendar year. You can disenroll from <Plan Name> between November 15 and December 31 of each year. Your disenrollment will be effective January 1 of the next year. You can’t disenroll between January 1 to March 31. You may not disenroll or make changes at other times unless you meet certain special exceptions, such as if you move out of the plan’s service area, qualify for Medicaid, or qualify for Extra Help with Medicare prescription drug costs. Those who disenroll during the calendar year will owe a portion of the account deposit back to the plan.”

- Include these statements to explain a member’s tax responsibility:

“You must file Form 1040, US Individual Income Tax Return, along with Form 8853, “Archer MSA and Long-Term Care Insurance Contracts” with the Internal Revenue Service (IRS) for any distributions made from your Medicare MSA account to ensure you aren’t taxed on your MSA account withdrawals. You must file these tax forms for any year in which an MSA account withdrawal is made, even if you have no taxable income or other reason for filling a Form 1040. MSA account withdrawals for qualified medical expenses are tax free, while account withdrawals for non-medical expenses are subject to both income tax and a 50 percent tax penalty.”

- Include the following language with the associated links to members for their information:

- **“For more information about MSA plans, visit www.medicare.gov/Publications/Pubs/pdf/11206.pdf to view the booklet “Your Guide to Medicare Medical Savings Account Plans;” and**

- **“Tax publications are available on the IRS website at <http://www.irs.gov> or from 1-800-TAX-FORM (1-800-829-3676).**

140.3 - Outbound Education and Verification Calls

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

42 CFR 422.2272

The MSA plan sponsor is required to make and record (or otherwise document) outbound education calls to all beneficiaries requesting enrollment (except those joining employer/union sponsored MSA plans) to ensure that they understand the plan rules and verify eligibility.

MAOs offering MSA plans should also ensure that enrollees understand that:

- A MSA trustee account must be opened in their name as part of the enrollment process so that it can be funded with the deposit for the plan year;
- A prorated portion of that deposit will be recovered by the plan on Medicare’s behalf if circumstances require a mid-year disenrollment;
- The money in this account may be used by the member and is tax exempt if used for qualified medical expenses;
- Only Medicare Part A and Part B expenses generally count towards the plan deductible; and
- The enrollee should never be asked to pay more than the Medicare allowed amount.

The MSA plan sponsors are reminded that all scripts must be submitted to CMS for review via HPMS. For additional information on the submission of marketing materials, please consult §80.

150 - Use Of Medicare Mark For Part D Plans

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 1140 of the Social Security Act

This section provides information and instructions to plan sponsors on the use of the Medicare Prescription Drug Benefit Program Mark.

150.1 - Authorized Users for Medicare Mark

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 1140 of the Social Security Act

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

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

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 1140 of the Social Security Act

All PDP and MA-PD entities may use the Medicare Prescription Drug Benefit Program Mark on items they distribute, provided the item(s) follow(s) guidelines for nominal gifts, as provided in §§20 and 70.2. Items with the Medicare Prescription Drug Benefit Program Mark cannot be sold for profit.

150.3 - Approval to Use the Medicare Prescription Drug Benefit Program Mark

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 1140 of the Social Security Act

CMS has established the following process to grant authorized users the use and access to the Medicare Prescription Drug Benefit Program Mark on Part D marketing materials.

For those organizations that have received "conditional approval" of a Part D plan via the CMS application and HPMS contract approval process, CMS will distribute the Medicare Prescription Drug Benefit Program Mark licensing agreement to those entities. Organizations are to certify/attest that they will use the mark according to the guidance in this chapter. After CMS has received the signed licensing agreement back from the organizations, the Medicare Mark URL will be sent to the organizations.

After receipt of the URL, organizations may begin using the mark on marketing materials (including the Part D membership ID card) that are required to be submitted to CMS for review.

Organization requests to distribute other items (i.e., materials that are not included in this chapter) bearing the Medicare Prescription Drug Benefit Program Mark must be submitted to CMS at least 30 days prior to the anticipated date of distribution. Requests should be sent to: CMS External Affairs Office/Visual & Multimedia Communications Group at 7500 Security Blvd., Baltimore, MD 21244-1850, Mail Stop: C1-16-03.

Once a request has been approved the following will apply: 1) approval will be effective for a period not to exceed one year or at the time of termination from the Part D program, and 2) approval will be granted only for those items for which use of the mark was requested in the request letter and for which written approval was granted.

150.4 - Restrictions on Use of Medicare Prescription Drug Benefit Program Mark

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 1140 of the Social Security Act

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

Unauthorized use of the Medicare Prescription Drug Benefit Program Mark should be reported immediately so that appropriate legal action can be taken. Reports of unauthorized use should be referred to CMS's External Affairs Office at 7500 Security Blvd., C1-16-03, Baltimore, MD 21244-1850, or by telephone to 410-786.7214.

150.5 - Prohibition on Misuse of the Medicare Prescription Drug Benefit Program Mark

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 1140 of the Social Security Act and 42 U.S.C. §1320b-10

Section 42 U.S.C. 1320b-10 prohibits the misuse of the Medicare name and marks. In general, it authorizes the Inspector General of the Department of Health and Human Services (DHHS) to impose penalties on any person who misuses the term Medicare or other names associated with DHHS in a manner which the person knows or should know gives the false impression that it is approved, endorsed, or authorized by DHHS. Offenders are subject to fines of up to \$5,000 per violation or in the case of a broadcast or telecast violation, \$25,000.

150.6 - Mark Guidelines

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 1140 of the Social Security Act

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



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

150.6.1 - Mark Guidelines - Negative Program Mark

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 1140 of the Social Security Act

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



150.6.2 - Mark Guidelines - Approved Colors

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 1140 of the Social Security Act

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



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



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



150.6.3 - Mark Guidelines on Languages

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 1140 of the Social Security Act

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



150.6.4 - Mark Guidelines on Size

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 1140 of the Social Security Act

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



150.6.5 - Mark Guidelines on Clear Space Allocation

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 1140 of the Social Security Act

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



150.6.6 - Mark Guidelines on Bleed Edge Indicator

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 1140 of the Social Security Act

The Program Mark may not bleed off any edge of the item. The mark should sit at least one-eighth (1/8) inch inside any edges of the item.

150.6.7 - Mark Guidelines on Incorrect Use

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 1140 of the Social Security Act

Following are rules for preventing incorrect use of the Medicare Prescription Drug Benefit Program Mark:

- Do not alter the position of the mark elements;
- Do not alter the aspect ratio of the certification mark. Do not stretch or distort the mark;
- Always use the mark as provided;
- Do not rotate the mark or any of its elements;
- Do not alter or change the typeface of the mark;
- Do not alter the color of any of the mark elements;
- Do not position the mark near other items or images. Maintain the clear space allocation;
- Do not position the mark to bleed off any edge. Maintain one-eighth (1/8) inch safety from any edge;
- Do not use any of the mark elements to create a new mark or graphic; and
- Do not use the mark on background colors, images or other artwork that interfere with the legibility of the mark.

150.7 - Part D Standard Pharmacy ID Card Design

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Section 1140 of the Social Security Act

Usage of the Medicare Prescription Drug Benefit Program Mark on any item must be consistent with §60.2 of this chapter.

Part D Plan Sponsor Name/Logo

sponsor
logo
place-
holder

RxBin 999999

RxPCN ABC1234567

RxGrp ABC123456789

Issuer (80840)

ID 12345678901

Name JOHN Q PUBLIC

Medicare_{Rx}
Prescription Drug Coverage

CMS - S5555 XXXX

Appendices

Summary of Medicare Advantage

And

Prescription Drug Plan

Technical Instructions

NOTE:

These appendices contain only CMS technical instructions/guidance related to items in this chapter. CMS model documents are not included in this chapter, therefore, all interested parties should reference the following web links for the specific CMS model documents:

For Part D model documents:

<http://www.cms.hhs.gov/PrescriptionDrugCovContra/PartDMMM/list.asp#TopOfPage>

For Part C model documents:

http://www.cms.hhs.gov/ManagedCareMarketing/09_MarketngModelsStandardDocumentsandEducationalMaterial.asp#TopOfPage

Appendix 1: Summary of Benefits

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

[Applies to MA-PD, PDP and MA only]

General requirements and guidance for SB are provided below:

1. Organizations must adhere to the language and format of the standardized SB and are permitted to make changes only if approved by CMS. Changes in the language and format of the SB template will result in the disapproval of the SB.
2. The title “Summary of Benefits” and the organization’s CMS contract number 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 1 and 2 if Section 3 is not being utilized).
4. The entire SB must be submitted for review as one document. If plans opt to utilize the premium table and/or Section 3, the entire SB will receive a forty-five (45) day review.
5. Front and back cover pages are acceptable.
6. Font size of 12 point or larger must be used for the SB (including footnotes). Organizations may use bold or capitalized text to aid in readability, provided that these changes do not steer beneficiaries to, or away from, particular benefit items or interfere with the legibility of the document.
NOTE: Since Sections 1 and 2 of the SB will not be generated from the PBP in 12 point font, the MA organization should change the font to ensure that the font size is 12 point.
7. Colors and shading techniques are permitted, but must not direct a beneficiary to or away from particular benefit item and must not interfere with the legibility of the document.
8. The SB may be printed in either portrait or landscape page format.
9. Organizations offering more than one plan may describe several plans in the same document by displaying the benefits for different plans in separate columns within the benefit comparison matrix (e.g., MA vs. MA-PD) (Section 2). However since the PBP will only print Sections 1 and 2 of the SB report for one plan, the organizations will have to create a side-by-side comparison matrix for two (or more) plans by

manually combining the information into a chart format. Organizations using this format must include the following statement in Section 1: **“Where is <the plan name> available?”: “There is more than one plan listed in this Summary of Benefits. If you are enrolled in one plan and wish to switch to another plan, you may do so only during certain times of the year. Please call Customer Service for more information.”** Since information in section 1 will conflict between MA and MA-PD plans, organizations will need to make a hard copy change for section 1 in order to reflect accurate information. These side-by-side comparisons are eligible for a 10-day marketing review if no other changes are made to the standardized SB.

10. Organizations offering plans with identical benefits within one contract (e.g., one contract S/H/R number), may display the information for these plans in the same column within the benefit comparison matrix (Section 2). Organizations using this format must include the following statement in Section 1: **“Where is <plan name> available?”: “If you move out of the state or county where you currently live to a state listed above, you must call Customer Service to update your information. If you don’t, you may be disenrolled from <plan name>. If you move to a state not listed above, please call Customer Service to find out if <plan org> has a plan in your new state or county.”**
11. If the SB describes only one of several plans offered by the organization, the availability of other plans must be noted in the Annual Notice of Change (ANOC).
12. If the SB describes more than one plan, the organization must identify the specific plan in which the member is currently enrolled within the ANOC included with the SB.
13. Organizations may include additional information about covered benefits within a separate flyer or other material and may provide this with the SB.
14. The SB header containing such information as the company name, customer service telephone number, only displays on the first page of the SB Section 2. It is acceptable for organizations to display the SB header on each page or on each section of the SB. PDPs will not need to print the auto-generated headings which include the S number, PBP number and segment numbers.
15. If an organization chooses to submit an SB for CMS review, without section 3 and no hard copy changes, it will be treated as a model without modification and will be reviewed within the 10 day time frame.

Additional General Instructions for MA/MA-PD Plans Only [Applies to MA-PD only and MA only]

1. If an MA organization wants to include mandatory supplemental benefits beyond those benefits found in the benefit comparison matrix, the MA organization must place the information in Section 3 of the SB. The MA organization must include a

brief description of the benefits and any co-pay requirements.

2. If the MA organization includes additional information about covered benefits in Section 3, the MA organization may include a page reference to this information in the appropriate box in the benefit comparison matrix using the following sentence: **“See page < > for information about <benefit category>. Please enter the benefit category exactly as it appears in the left column).”**

Instructions for Section 1 – Beneficiary Information **[Applies to MA-PD, PDP and MA only]**

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

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

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

1. Section 1, as generated by the PBP, will include the applicable H number and plan number at the top of the document. MA organizations must delete this information.
2. The fourth paragraph (How can I compare my options?) contains a sentence **“We also offer additional benefits, which may change from year to year.”** If this is not applicable to your plan, you must remove this sentence.
3. The second question and answer in section 1 includes the plan’s service area; the PBP will generate a list of counties, with an * indicating those counties that are partial counties. The MA organization may list the zip codes of these counties in this section or provide a cross-reference in section 3 and list the zip codes here. The MA organization must also explain in section 1 that the * indicates a partial county.
4. The second question and answer in section 1 lists the plan’s service area, but does not indicate that the information listed represents counties. Therefore, the MA organization must amend the SB so that the answer reads, **“The service area for this plan includes the following counties: <list of counties automatically generated by the PBP>.”**
5. Refer to #s 9 and 10 in the SB General Instruction section above for information on additional sentence requirements for Section 1 of the SB.

Instructions for Section 2 – Benefit Comparison Matrix

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

Instructions for Section 3 – Plan-Specific Features

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

This section is limited to a maximum of six pages of text and graphics. The page limit is defined as 6 single-sided pages or three double-sided pages. However, there is one exception to this limit: Organizations translating the SB to another language may add pages as necessary to ensure the translation conveys the same information as the English language version.

Organizations may provide additional information in Section 3 about covered benefits described within the benefit comparison matrix. If the organization chooses to further describe its covered benefits in Section 3, it may reference the information in the relevant section of the benefit comparison matrix using the following sentence: **“See page < > for additional information about (Enter benefit category exactly as it appears in the left column.)”**

All information included in Section 3 must be verified with the information entered into the PBP report in HPMS.

Instructions for Use of Premium Tables in the Summary of Benefits [Applies to MA-PD, PDP and MA only]

Plans with identical benefits offered in different regions may combine their SB even if their premiums vary between plans by following the requirements below:

- In Section 2: Benefit Comparison Matrix, plans must indicate the premium range for all plans listed in the SB. In addition, plans must include a note directing the reader to a **“Premium Table”** that reads **“Please refer to the Premium Table after this section to find out the premium is in your area.”**
- The **“Premium Table”** should be located after Section 2 and before Section 3. The table must include only the plan’s name, number, service area and premium. Plans may include introductory information about the table and how to use it. However, no other plan information may be included with the **“Premium Table.”**

SBs with only Sections 1, 2 and the Premium Table are subject to a 45-day review.

Requests to Change Hard Copy Summary of Benefits

[Applies to all organizations/plan types]

CMS will allow an organization to make changes to hard copy SBs on a very limited basis. All organizations must obtain hard copy change request approval prior to submitting their SBs to CMS for review.

NOTE:

- Hard copy change requests related to the description of benefits should not be submitted until CMS has approved all bids;
- Plans may submit administrative hard copy requests (e.g., changes to local phone or website location) prior to the bid approval;
- Hard copy changes are only permitted to correct inaccurate or misleading information or errors generated from the PBP/SB software;
- CMS will not allow changes in wording based on individual preferences;
- The fact that a hard copy change request was approved in a prior year is no guarantee that it will be approved in a subsequent year;
- Any approved hard copy changes will not result in changes to the Medicare Options Compare or to the Plan Benefit Package (PBP);
- Plans should validate the data entered in the PBP as well as reference the SB crosswalk to ensure the correct sentences are generated for the specific benefit being described; and
- Hard copy changes will not be considered once the PBP is closed for corrections

How to Request a Change

[Applies to MA, MA-PD and PDP]

To request a change to the hard copy SB, MA, MA-PD or PDP should send an e-mail to SummaryofBenefits@cms.hhs.gov. The subject line in the request must read: **“Hard Copy Change Request for H/M/R/S/ <number>, PBP <number or range>.”** In the body of the e-mail, MA or MA-PD should provide:

- The contract number and PBP #(s) and the regional office reviewer responsible for SB review;

- If the request for change applies to multiple H numbers and plan IDs, the plan may include all applicable H numbers and plan IDs in one e-mail;
- The existing standardized Summary of Benefits language;
- An explanation of why the existing standardized language is inaccurate; and
- A modified sentence.

Summary of Benefits for 1876 Cost Plans **[Applies to 1876 Cost plans – see information below]**

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

General Instructions

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

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

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

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

Instructions for Section 1- Beneficiary Information Section

For Cost plans that are “closed” to new enrollment, the pre-enrollment language in Section 1 will not apply **to existing members**. Therefore, these Cost plans should include the following disclaimer in their ANOC: **“Existing Cost Plan members should disregard the Introduction of Section 1 of the Summary of Benefits (SB).”**

NOTE: Any additional information regarding the contractor’s “closed status” should also be included in the cover letter.

CMS requires the Summary of Benefits (SB) to be used in both pre-enrollment and annual notice of change (ANOC) functions.

Instructions for Section 2 - Benefit Comparison Matrix

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

“If you go to a provider outside of <insert name of plan>’s network who accepts Medicare patients, you’re covered under Original Medicare. You would pay the Part A and Part B deductibles and coinsurance..”

Appendix 2: Attestation Form for Translated Non-English Materials or Alternate Materials

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

Below is the model attestation for translation of Non-English or Alternate Materials that plan sponsors must submit to CMS.

ATTESTATION OF TRANSLATED NON-ENGLISH MATERIALS OR ALTERNATE MATERIALS

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

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

The organization is submitting to CMS the attestation with the following materials:
<INSERT MATERIAL IDENTIFICATION NUMBERS>

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

(Name & Title <CEO, CFO, or designee able to legally bind the organization>)

On behalf of

(Name of Organization)

Date

Appendix 3: Plan Sponsor Website Must Use Chart

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

The following Must Use/Must Not Use Chart applies only to URL guidelines and Part D plan website content requirements. Please refer to the applicable sections for specific marketing requirements pertaining to other marketing materials.

Subject		Must Use	Must Not Use	Reason
	URL Guidelines	<p>All Part D plans must maintain a Web page, or, if they choose, a Website dedicated to the Part D program.</p> <p>All marketing materials can include a Web address that connects to either a corporate Website or to the plan's Part D Web page.</p>		Beneficiaries should be able to find a Part D plan's program information with a minimum of difficulty.
	Website Links	<p>All links on a Part D plan's Website must be clearly labeled with navigational icons that indicate the information contained in the link.</p> <p>Any links to health-related or non-health related products/services must be clearly labeled as such.</p>	Links to foreign drug sales	It should be clear to beneficiary how to navigate the Website.
	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 Website must contain the Part D plan's toll-free customer service number, TTY 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.

Subject		Must Use	Must Not Use	Reason
	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.		
	Benefits	<ul style="list-style-type: none"> • 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	<ul style="list-style-type: none"> • Name addresses phone number and type of pharmacy for all non-chain pharmacies. For chain pharmacies, a local or toll-free number and a TTY 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.") <p>If organizations use a search engine on their Websites in lieu of posting the Pharmacy Directory, the search engine must include all of the requirements in Section 6 (Marketing Material Development).</p>		
	Current Formulary	<p>All plans must include a current formulary, updated at least monthly.</p> <p>For formulary requirements, please refer to Section 6 (Marketing Material Development)</p>		

	Subject	Must Use	Must Not Use	Reason
	Out-of-Network Coverage	All plans must include provisions for non-routine access to covered Part D drugs at out-of-network pharmacies, including limits and financial responsibility for access to these drugs.		
	Grievance, Exceptions, Coverage Determinations and Appeals Procedures	<p>On their Website, <i>all plans must include a description of their grievance, coverage determinations (including exceptions), and appeals</i> processes, and the procedures plan members must follow to file a grievance or request a coverage determination (including an exception) or an appeal.</p> <p>Part D organizations must include specific information on a Web page (located as close to the plan's formulary page as possible) developed specifically for exceptions and appeal.</p>		
	Quality Assurance Policies and Procedures	All plans must include a description of their quality assurance policies and procedures, including medication therapy management, and drug and/or utilization management.		
	Potential for Contract Termination	All plans must include a notice of possible contract termination or reduction in service area and the effect these actions may have on its members.		
	Required Links	<p>The following documents must be accessible by links:</p> <ul style="list-style-type: none"> • Summary of Benefits • Enrollment Instructions and Forms • Evidence of Coverage • Privacy Notice • Plan Transition Process 		These materials are required for beneficiaries to be able to make an informed choice and to enroll in a particular program.

	Subject	Must Use	Must Not Use	Reason
	<p>If applicable: Notice of Formulary Change</p>	<p>Plans must provide notice on their Website regarding removal or change in the preferred or tiered cost sharing status of a Part D drug.</p> <p>The notice must contain the following:</p> <ul style="list-style-type: none"> • 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. 		

Appendix 4: Model File & Use Certification Form

(Rev. 91; Issued: 08-07-09; Effective/Implementation Date: 08-07-09)

[Applicable to MA, MA-PD, MA only, 1876 Cost Plans]

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

I agree that CMS may inspect any and all information including those held at the premises of the Medicare health plan to ensure compliance with these requirements. I further agree to notify CMS immediately if I become aware of any circumstances that indicate noncompliance with the requirements described above.

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

Signature

Name & Title <CEO, CFO, or designee able to legally bind the organization>
On behalf of

Name of Medicare Health Plan

Date

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