
CMS Manual System

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

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Date: May 17, 2011

SUBJECT: Chapter 3.” Medicare Marketing Guidelines”

I. SUMMARY OF CHANGES: CMS has revised the Medicare Marketing Manual to include clarifying existing language and incorporating recent policy issuances needed to enhance marketing operations under both the MA and Part D programs. We have also made minor editorial changes throughout the document to include new additions and/or renumbering of sections, deletions of certain sentences or word in a section, and formatting of some sections to ensure consistency within the chapter.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: May 17, 2011

IMPLEMENTATION DATE: May 17, 2011

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only One Per Row.)

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III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

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***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 Section 1876 Cost Plans

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10 – Introduction

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

These Medicare Marketing Guidelines (*MMG*) reflect the Centers for Medicare & Medicaid Services' (CMS) current interpretation of the marketing requirements and related provisions of the Medicare Advantage (MA), Medicare Prescription Drug Plan (PDP) rules *and 1876 cost contracts* (Chapter 42 of the Code of Federal Regulations, Parts 422, 423 *and 417*). These Medicare Marketing Guidelines are for use by Medicare Advantage organizations offering MA plans and MA prescription drug (MA-PD) plans, section 1876 cost contracts, and Prescription Drug plan (PDP) sponsors. These Medicare Marketing Guidelines are not applicable to 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 or to section 1833 cost plans.

The scope of the term marketing, as used in the Medicare statute at Section 1851(h) and 1860D-12(b)(3)(D)(12) of the Act and CMS regulations extends beyond the public's general concept of advertising materials. Pursuant to 42 CFR §§ 422.2260, and 423.2260 marketing materials include any informational materials targeted to Medicare beneficiaries.

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 steer or attempt to steer a potential enrollee toward 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 encompasses various materials and activities.

It is important to note that the marketing guidance set forth in this document is subject to change as policy, communication technology and industry marketing practices continue to evolve. It is the plan sponsor's responsibility to have a system in place that ensures all materials used in the marketplace meet current regulations and guidelines. Moreover, the examples of marketing materials and promotional activities given in these Medicare Marketing Guidelines are not all-inclusive. Plan sponsors should apply the principles outlined in these Medicare Marketing Guidelines to all relevant decisions, situations, and materials. Any new rule-making or interpretative guidance (e.g., annual call letter or Health Plan Management System (HPMS) guidance memoranda) may update the marketing guidance provided here, and plan sponsors should use sound judgment and consult with CMS Account Managers 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. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2, 422.4, 423.4, 422.2260, 423.2260, 422.2264, 423.2264, 422.2268, 423.2268, 422.2272, 423.2272

The following definitions apply for purposes of these Medicare Marketing Guidelines only.

Ad-hoc Enrollee Communications Materials

Ad-hoc enrollee communications materials are informational materials that are targeted to current enrollees, are customized or limited to a subset of enrollees, or apply to a specific situation, and which do not include information about the plan's benefit structure, but apply to specific situations or cover member-specific claims processing or other operational issues. These materials are not considered marketing materials. Examples of these materials include the following:

- Letters about a shortage of formulary drugs due to a manufacturer recall letter;
- Letters to communicate that a beneficiary is receiving a refund or is being billed for underpayments;
- Letters describing member-specific claims processing issues; *and*
- *Customer service correspondence pertaining to unique questions or issues that affect an individual or small subset of the plan's enrollment.*

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
- Direct mail items such as postcards, self mailers, home delivery coupons, and reply cards *as* long as they do not include enrollment forms.

Alternate Formats

Alternate formats are used to convey information to beneficiaries with disabilities (e.g., Braille, large print, and audio).

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 Medicare Marketing 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 to enroll or 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 in the plan. Co-branding relationships are entered into independent *of* 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 are required to have a website with the web address provided in the HPMS contract management module. 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.

Direct mail

Is information sent to a beneficiary to attract attention or interest to a potential enrollee and allow him/her to request additional information.

Education

Informing a beneficiary about Original Medicare, MA plans, MA-PD plans or PDPs in an unbiased way that does not steer, or attempt to steer, that enrollee toward a specific plan or limited number of plans.

Educational Event

An event designed to inform Medicare beneficiaries about Medicare Advantage, Prescription Drug or other Medicare programs that does not steer, or attempt to steer, potential enrollees toward a specific plan or limited number of plans. Educational events may be hosted by the plan sponsor or an outside entity and are held in a public venue. 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 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.)

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 *notices*.

NOTE: Refer to Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the Prescription Drug Benefit Manual for model enrollment forms and notices.

Health Plan Management System (HPMS)

A web-enabled information system that serves a critical role in supporting the implementation and ongoing operations of MA plans, MA-PD plans, section 1876 cost plans and PDPs. HPMS and its software modules are used to collect, *track, trend and analyze plan and CMS* 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) plan 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. Plan sponsors may choose the counties in which local plans 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.

NOTE: PDPs **cannot** offer a local plan.

Marketing

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

CMS’ authority for marketing oversight includes 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.

- Communications to members about contractual changes, and changes in providers, premiums, benefits, plan procedures, etc.
- Membership activities (for example, materials *on plan policies, procedures*, rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or non-claim specific notification information.)
- The activities of a plan sponsor's employees, independent agents or brokers, subcontracted *TMOs* or other similar type organizations that are contributing to the steering of a potential enrollee toward 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 Medicare Marketing Guidelines, extends beyond the public's general concept of advertising materials. Marketing materials include any informational materials targeted to Medicare beneficiaries which:

- Promote the plan sponsor, or any MA plan, MA-PD plan, section 1876 cost plan, or PDP offered by the plan sponsor.
- Inform Medicare beneficiaries that they may enroll, or remain enrolled in, an MA plan, *MA-PD plan, section 1876 cost plan*, or PDP offered by the plan sponsor.
- Explain the benefits of enrollment in an MA plan, MA-PD plan, section 1876 cost plan, or PDP or rules that apply to enrollees.
- Explain how Medicare services are covered under an MA plan, MA-PD plan, section 1876 cost plan or PDP plan, including conditions that apply to such coverage.

Marketing/Sales Event

Marketing/sales events are events *designed to steer, or attempt to steer, potential enrollees toward a plan or a limited set of plans. At marketing/sales events the plan sponsor may* promote specific benefits/premiums and/or services offered by the plan. Plan sponsors may conduct a formal event where a presentation is provided to Medicare beneficiaries or an informal event where plan sponsors are only distributing health plan brochures and pre-enrollment materials. Plan sponsors may also accept enrollment forms and perform enrollment at marketing/sales events.

Marketing Appointments

Marketing appointments are individual appointments designed to steer or, attempt to steer, potential enrollees toward a plan or limited number of plans. All individual appointments between an agent and a beneficiary are considered marketing/sales appointments regardless of the content discussed.

Medicare Advantage (MA) Organization

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 (MA) Plan

A plan that offers coverage of Medicare Part A and Part B benefits, and which may also offer other benefits, including Part D coverage, at a uniform premium and uniform level of cost-sharing to individuals living in the service area who are entitled to benefits under Medicare Part A and enrolled in Part B.

Medicare Advantage Prescription Drug (MA-PD) Plan

An MA plan that provides qualified prescription drug coverage.

Medigap

A Medicare supplemental (Medigap) policy is a health insurance policy sold by private insurance companies specifically to fill “gaps” in Original Medicare coverage. A Medigap policy typically pays some or all of the deductible and coinsurance amounts applicable to Medicare-covered services and sometimes covers items and services that are not covered by Medicare, such as care outside of the country.

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 receive a shorter review period or to submit under File & Use as outlined in § 90.6.1. The use of CMS model documents is optional unless otherwise directed by CMS or if the material falls into the category of standardized model materials (refer to § 90.7.2). Plan sponsors that choose to create their own language 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 status.

National Plans:

- **National PDPs:** The term “national plan” means a PDP sponsor that, at a minimum, offers 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 (e.g., 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.)

- **National Medicare Advantage and Medicare Advantage Prescription Drug MAs/MA-PDs Plans:** The term “national plan” means a Medicare Advantage Organization (MAO) that offers MA/MA-PD plans in each of the 50 States and the District of Columbia. An MA or MA-PD is considered to be a national plan regardless of whether or not the MAO offers a plan in one or more of the territories.

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 *either an individual item worth \$15 or less, or aggregate items throughout the year worth \$50 or less, where prices are based on the retail purchase price of the item. Note that CMS sets the maximum, not the minimum for nominal gifts. Please refer to § 70.2 for the definition of a pre-enrollment promotional gift which differs slightly from that of a post-enrollment reward.*

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

A term used to describe the program encompassed by all plan sponsors offering MA or MA-PD coverage.

Part D Program

A term used to describe the program encompassed by all plan sponsors offering Part D prescription drug coverage.

Part D Sponsor or Part D Plan Sponsor

A Part D sponsor is an MAO that offers an MA-PD plan, a PDP sponsor offering a PDP, or a section 1876 cost plan offering qualified prescription drug coverage.

Plan Benefit Package (PBP)

The package of benefits to be offered in a specific geographic area by *a sponsor under* an MA plan, MA-PD plan, PDP, section 1876 cost plan or employer group waiver plan, filed annually with CMS for approval.

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

Plan Sponsor

The term “plan sponsor” is utilized in these Medicare Marketing 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 section 1876 cost plans.

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

Post-Enrollment Marketing Materials

A subset of explanatory marketing materials used by a plan sponsor to convey benefits or operational information to current enrollees. 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
- Member handbook
- *Explanation of Benefits (EOB)*

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
- Summary of Benefits (SB)

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.

Provider

For purposes of the MMG, the term provider includes all providers contracted with the plan sponsor, non-contracted providers, sub-contractors, including, but not limited to, pharmacists, pharmacies, physicians, hospitals and long-term care facilities.

Regional Plans

- **PDP Regional Plan:** 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:** An 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 Medicare Marketing Guidelines to define an individual who markets and/or sells products for a single plan sponsor or numerous plan sponsors. It includes employees, brokers, agents, and all other individuals, entities, and downstream contractors that may be utilized to market and/or sell on behalf of a plan sponsor.

Section 1876 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 of the Social Security Act.

Standardized Language

Language developed by CMS or other Federal agencies which is mandatory for use by the plan sponsor and **cannot** be modified *except as noted within the relevant document(e.g., ANOC/EOC, SB, Plan Ratings)*.

State Pharmaceutical Assistance Program (SPAP)

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

Template Materials

A template material is any marketing material that includes placeholders for variable data to be populated at a later time.

Third Party Marketing Organization (TMO)

An entity such as a Field Marketing Organization (FMO), General Agent (GA), or similar type of organization that has been retained to sell or promote a plan sponsor’s Medicare products on the plan sponsor’s behalf either directly or through sales agents or a combination of both.

Value Added Items and Services (VAIS)

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 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. *(See Chapter 4, section 60)*

30.1-Record Retention Requirements

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

*422.504(d), 422.504(d)(1)(i)-(vii), 422.504 (e), 422.504(h)1, 422.504(h)(2), 422.504(i)(1), 422.504(i)(2), 422.504(i)(3), 422.504(i)(4)(i)-(v), 422.504(i)(5)
423.504(d), 423.504((d)(1)(2), 423.505(h)(1), 423.505(h)(2), 423.505(h)(2)(i), 423.505(h)(2)(i)-(ii), 423.505(h)(3), 423.505(h)(i)-viii), 423.505(h)(4)(i)-(iv), 423.505(h)(5)*

All plan sponsors must abide by CMS rules and regulations regarding record retention by retaining documents (i.e. books, records and documents, etc.) for a period of ten (10) years. The retained documents should be sufficient to include all policy and operational procedures conducted during the course of the effective period of the CMS contract with the plan sponsor. Plan sponsors are responsible for ensuring that any marketing materials developed on behalf of the plan or by third party or delegated entities adhere to CMS record retention requirements. Any records that should be retained as a result of direction from the Department of Justice should be kept by plan sponsors and their affiliates.

30.2 - Limitations on Distribution of Marketing Materials

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 Metro Statistical Area that covers two regions), plan sponsors are required to clearly disclose their service area.

NOTE: Dual-Eligible (DE) SNPs are responsible for making sure that the service area in which they market is consistent with the service area included in applicable State contracts.

30.3 - Co-branding Requirements

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2268, 423.2268

CMS permits plan sponsors to enter into co-branding arrangements as provided in this section. 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 *in writing* of any co-branding relationships at the time that the plan sponsor begins to input the co-branding relationships in the Health Plan Management System (HPMS). The HPMS submission module will allow plan sponsors

to indicate whether they are co-branding with specific entities for specific services. (Refer to the HPMS user manual for instructions.)

- 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 references to and former co-branding partner(s) from its marketing materials as applicable.
- The plan sponsor is responsible for ensuring 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 Medicare Marketing Guidelines and that the co-branding partners agree to follow these guidelines with respect to all marketing materials related to the plan sponsor.

***NOTE:** CMS will provide additional guidance regarding the attestation requirements between the plan sponsor and the co-branding partner. We anticipate releasing this requirement in the HPMS contracting module for CY 2012.*

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).

30.3.1 - Co-branding with Network Providers

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 a member's selection of a specific provider/provider organization (for example, physicians, and hospitals).

Plan sponsors that choose to co-brand with network providers must include on marketing materials other than ID cards the following language:

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

All co-branding names and/or logos of providers and/or pharmacies should be on all other marketing materials. 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 Medicare Marketing Guidelines and must be submitted to CMS by the plan sponsor. Plan sponsors may elect to submit co-branded materials as template materials.

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

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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. The 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. 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. It is entirely the plan sponsor's decision whether or not to co-brand with the SPAP. 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 *sponsor'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, informs 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.

Entities with a co-branded relationship that involves remuneration between parties in a position to influence the referral of Medicare-payable business should carefully scrutinize the relationship for compliance with the fraud and abuse laws, including the Federal anti-kickback statute.

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

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2268, 423.2268

Plan sponsors whose legal or marketing names include the logos and/or names of network providers, or whose downstream entities' legal or marketing names include the logos and/or

names of network providers, are required to include the following *disclaimer* language on all of their marketing materials. Plan sponsors *must prominently display* the disclaimer *at the bottom of the first page of the material in similar font and style as the message.*

“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. *Additionally plan sponsors must include a statement that states “Other plans may be available in the service area”.*

30.5 - Use of Data from Medigap Issuers

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2268, 423.2268

If a Medigap issuer chooses to sponsor an MA plan, MA-PD plan, section 1876 cost plan, or PDP, it is permitted to use its current Medigap plan enrollment information to market the MA, MA-PD, cost, or Part D plan to those enrollees, to the extent permitted by the HIPAA Privacy Rule and other applicable Federal or State privacy laws. However in doing so, the Medigap issuer/plan sponsor may not conduct outbound calls to market its MA, MA-PD, cost or Part D plans. The Medigap issuer/plan sponsor may conduct other marketing activities related to its MA, MA-PD, cost or PDP plans to all current Medigap enrollees, not just a subset. Additionally, the Medigap issuer/plan sponsor must adhere to all HIPAA Privacy Rules and other applicable Federal or State privacy laws.

If during the course of an outbound call regarding Medigap products, the beneficiary initiates interest in an MA, MA-PD, cost plan, or PDP product offered by the Medigap issuer, then that MA, MA-PD, cost plan, or PDP product may be discussed, as long as the call is recorded. (Refer to § 70.4 on unsolicited contact.)

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

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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/union 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 (e.g., the MAO 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 Medicare Marketing Guidelines. 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.

Employer group health plans should refer to §130 of this chapter, § 20.3 of Chapter 9 of the Medicare Managed Care Manual, and § 20.3 of Chapter 12 of the Prescription Drug Benefit Manual for more guidance.

30.7 - Anti-Discrimination

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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

Plan sponsors may not discriminate based on race, ethnicity, *national origin*, religion, gender, *age, mental or physical* disability, health status, *claims experience, medical history, genetic information, evidence of insurability* 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 (LIS), as there may be additional eligibility standards.

NOTE: As provided in § 20.2 of Chapter 2 of the Medicare Managed Care Manual, an individual is generally not eligible to elect an MA plan if he/she has been medically determined to have ESRD.

Plan sponsors may not engage in discriminatory practices such as targeting marketing to beneficiaries from higher income areas. Additionally, plan sponsors may not state or otherwise imply that plans are available only to seniors rather than to all Medicare beneficiaries. Only SNP sponsors may limit enrollment to dual-eligibles, institutionalized individuals, or individuals with severe or disabling chronic conditions and/or may target items and services to corresponding categories of beneficiaries.

30.8 - Requirements for Plans with Non-English Speaking Populations

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2264(e), 423.2264(e)

All plan sponsors' call centers must have interpreter services available to call center personnel to answer questions from non-English speaking beneficiaries. Call centers are those centers that receive calls from current and prospective enrollees. This requirement is in place regardless of the percentage of non-English speaking beneficiaries in a service area.

Beginning with marketing materials for the 2012 AEP, plan sponsors must make the marketing materials noted in § 30.11, 30.12, 30.13 and the Part D Transition Letter available in any language that is the primary language of more than five (5) percent of a plan sponsor's plan benefit package service area. (NOTE: the member ID card is excluded from this requirement). Additionally, plan sponsors must place translated versions of these materials on the plan's website. For example, contract ID HXXXX includes plan 001. The plan sponsor's PBP service area would be the counties that are covered by plan 001. CMS expects plan sponsors operating in areas where the five (5) percent language requirement threshold is met will provide non-English materials upon beneficiary request. The referenced marketing documents for CY2011 marketing materials are subject to a ten (10) percent threshold.

CMS expects that translated versions of materials will be uploaded in HPMS and that requests for translated materials *will be fulfilled within* a reasonable timeframe. *When translating a material, plans should translate the final version of the English material, not a template of the English materials.*

CMS will verify the availability of non-English marketing materials through monitoring review, and will also periodically conduct accuracy reviews of non-English materials. If materials are unavailable, inaccurate, or do not convey the same information as the English version, plan sponsors may be subject to compliance or enforcement action and must cease use of these materials until revised materials have been approved.

Plan sponsors operating in service areas that do not meet the five (5) percent threshold are not required to produce any translated materials.

30.9-Requirements for Plans with Special Needs Populations

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

Basic enrollee information must be made available to individuals with disabilities (for example, those with visual or hearing impairments) upon beneficiary request. Plan sponsors must make sure information about their benefits is accessible and appropriate for Medicare beneficiaries who have disabilities.

30.10 - Compliance with Section 508 of the Rehabilitation Act

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 *and located at <http://www.section508.gov/>.*

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

30.11 - Required Materials in Enrollment Kit

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.111, 423.128

When a beneficiary is provided *enrollment instructions/form* for the purpose of enrollment/potential enrollment, the information listed below must be included. This, in total, represents an “Enrollment Kit.” When a plan sponsor enrolls a beneficiary online, it must make these materials available electronically (for example, via website links) to the potential member prior to the completion and submission of the enrollment request. Beneficiaries must have access to enrollment materials either electronically or *in* hard copy to ensure this information is received prior to completion of the enrollment request. Plan sponsors must ensure that all appropriate disclaimers are on the materials specified below (refer to § 50 for disclaimers).

NOTE: *If the information below is contained elsewhere in one of the documents of the enrollment kit, plans are not required to create a separate document containing that specific information.*

NOTE: *Inclusion of 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 is optional since the contact information is included in the SB.*

- Enrollment instructions and forms
- Written notice that plan benefits and cost-sharing may change from year to year. (Refer to § 50.1.3 for disclaimers regarding benefits)
- Written explanation of plan’s grievance, coverage/organization determination (including exceptions) and appeals processes, including differences between the processes and when it is appropriate to use each
- Plan ratings information on <http://www.medicare.gov> must be submitted as a standalone document. Refer to § 30.18 for more details about plan ratings information
- Summary of Benefits (SB)

Plan sponsors have the option of including the following materials in their enrollment kits but must make them available upon request. However, if a beneficiary enrolls with the plan sponsor, the materials below must be distributed to him/her no later than ten (10) calendar days from receipt of CMS confirmation of enrollment or by the last day of the first month of enrollment, whichever occurs first.

- Pharmacy directory (Part D sponsors only)
- Provider directory

- Combined provider/pharmacy directory (refer to § 60.4.4 for additional requirements)
- Comprehensive or abridged formulary (Part D sponsors only)

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

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.111, 423.128, 422.2264, 423.2264

Within the timeframes specified by CMS, plan sponsors must provide members with all necessary information outlined in Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual. In addition, the materials below must be distributed to a beneficiary no later than ten (10) calendar days from receipt of CMS confirmation of enrollment or by the last day of the first month of enrollment, whichever occurs first. Plans should refer to the notification on the Transaction Reply Report (TRR) that contains the earliest notification to identify the start of the ten (10) calendar day timeframe.

- Annual Notice Of Change /Evidence Of Coverage (ANOC/EOC) or EOC as applicable (except for DE SNPs; refer to § 60.7 for more information about these requirements);
- Comprehensive formulary or abridged formulary including information on how the beneficiary can obtain a complete formulary (Part D sponsors only)
- 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)

30.13 - Required Ongoing Materials for New and Renewing Members

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR *422.111 (b) (12)*, 423.128(e)

Plan sponsors offering *the* Part D *benefit* 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 benefit. Refer to § 60.6 for more information about the *Part D* EOB. *Additionally, CMS may require an MA organization to furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under Part 422. The explanation of benefits will be pilot tested in CY 2012, and CMS will provide updates to all plans following the pilot.*

30.14 - Hold Time Messages

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2268 (f) and 423.2268(f)

Hold time messages (recorded information played to *a* caller while waiting on hold) that discuss health-education features and other general information (e.g., hours of operation, flu shot reminders) are allowed. Hold time messages that include information regarding disease management programs or health education or other generic statements such as “Thank you for holding” will not require CMS review and approval. However, other health related features on hold time messages should be submitted for a forty-five (45) day review. Plan sponsors may not include *information on* non-health related services (e.g., financial service information) on hold time messages. Refer to § 80.1.4 for additional information on scripts.

30.15 - Use of the Medicare Name

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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,” or “Health and Human Services” in a manner that would convey the false impression that the business or product *mentioned* is approved, endorsed, or authorized by Medicare or any other government agency. This rule extends to downstream contractors that 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.

30.16 - Referral Programs

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 encourage 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 may use member provided referral names and addresses to solicit potential new members by mail only.
- 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.
- Plan sponsors may offer thank you gifts *provided they are each individually* worth \$15 or less *and in the aggregate for the year worth \$50 or less where price is* 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.

30.17 - Privacy and Confidentiality

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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

Plan *sponsors* 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 (e.g., health screening or “cherry picking”). HIPAA and privacy documents (e.g., a HIPAA/privacy document for a beneficiary's signature in a provider's office) are not considered marketing documents and therefore do not need to be submitted in HPMS. Refer to § 90.21 regarding materials not subject to review. Additional information on the HIPAA Privacy Rule and its disclosure requirements can be found at <http://www.hhs.gov/ocr/privacy/>.

30.18 - Plan Ratings Information from www.medicare.gov.

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 and other measures. 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 enrollment kits, making it available *on websites and* upon request. Information from <http://www.medicare.gov> and the HPMS generated plan ratings document described below may not be altered in any way *except as noted below*.

Plan sponsors must download their plan performance rating *information* generated from the HPMS Part D Performance Metrics Module using the following navigation path: HPMS Homepage>Quality and Performance>Part D Performance Metrics and Reports> Plan Ratings Template. Plan sponsors will select their contract number from the list and click on the “Create PDF” link to generate their customized contract-specific template in PDF format, which may not be altered. Plan performance summary ratings for each upcoming contract year will be available *in* the fall of each year. *Once the plan rating information is downloaded, plan sponsors must add the relevant ratings year to the top of the document and may also add the plan logo. The plan*

rating information should be submitted as File & Use under category code 9004. The material ID must be included on the front page of the plan ratings information document.

Plan performance summary ratings *are issued in October of the previous plan year. Until such time as the plan rating information for the following contract year is made available, plan sponsors must provide the current year's plan ratings information* (which is generated from HPMS), and include them in their enrollment *kits and on websites*. Once the *upcoming year's plan performance rating template is available, plan sponsors must download the template and submit as File & Use as described above (e.g. the document can be used 5 days after submission)*. Plan sponsors must *update their websites to include the new plan performance rating and update information in their enrollment kit no later than 30 days after the release of the upcoming year's ratings* to ensure *that the most recent plan performance ratings are provided to existing and prospective enrollees. All marketing during the Annual Enrollment Period should use the plan performance summary rating for the upcoming year. New plans that do not have any plan ratings information are not required to provide plan ratings information until the new contract year.*

References to star ratings in marketing and/or enrollment materials other than the HPMS-generated plan rating information must include the year for which the plan's summary star rating applies (e.g., "xx plan is a 2011 5-Star rated plan"). Plans should also include the following disclaimer on marketing and enrollment materials that refer to its star ratings: "Plan performance summary star ratings are assessed each year and may change from one year to the next."

NOTE: *Plan sponsors are responsible for translating plan ratings information as specified in § 30.8. Translation of plan ratings information will not be considered an alteration of the document. Additionally, EGWPs are excluded from this requirement.*

30.19 – Extended Marketing Period for Plans With Five-Star Ratings

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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

As noted above, plan performance summary star ratings apply to plan sponsors for the plan contract year (January – December). Plans with a five-star summary rating may market to and enroll beneficiaries throughout the year, with enrollment under the Five-Star Special Enrollment Period (SEP) taking effect on the first day of the subsequent month during the period for which the plan has the five-star rating (January 1 – December 1).

If a plan sponsor with a summary rating of five stars during the current year is assessed a summary rating of less than five stars for the upcoming year, the plan sponsor must discontinue marketing for the purposes of accepting enrollments under the Five-Star SEP by November 30 of the current year.

40.1 - Marketing Material Identification Number

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 *including standardized OMB forms*. 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 a Medicare marketing material. *Except as noted below, the material ID must be entered into HPMS in the same manner that it appears on the marketing material.*

The material ID is made up of three parts. The first part of the material identification number is the plan sponsors' contract number (H for MA or section 1876 cost plans, R for regional PPO plans (RPPOs), or S for PDPs) or Multi-Contract Entity (MCE) identifier (Y) followed by an underscore. The second part of the identifier is any series of alpha numeric characters chosen at the discretion of the plan sponsor. The third part includes either the term "CMS Approved" or the term "File & Use," as appropriate, with a placeholder for the date (i.e., two digits each for month and day, followed by a four digit year.) (For example "Y1234_drugx38 CMS Approved MMDDYYYY.") *This third part of the identifier must be included on the material, but is not required to be included in the material ID that is submitted into HPMS.* The unique material ID must be printed on the front page of all materials, including the SB and ANOC/EOC. The ID should be positioned in the lower left or right hand corner on the front page of the material and be in twelve (12)-point font.

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. The marketing material ID is, therefore, not needed on the member ID card. Additionally, *envelopes*, television and radio ads, outdoor advertisements, and banner or banner-like ads (including Internet banner ads) are not required to include the material ID. All other materials should have the material ID which includes the placeholder for a CMS approval or File & Use date.

Use of the *contract* number (i.e., H, R, or S) will allow the plan sponsor to submit marketing material that applies to only one contract while use of the MCE identifier of (Y) will allow the plan sponsor to submit marketing material that applies to multiple contract numbers. When submitting material using the MCE identifier, plan sponsors are not required to include the individual contract numbers in the material ID to which the material applies. Refer to § 90.15 *for* additional guidance on the MCEs.

After the material is approved, accepted for File & Use, or deemed approved, the plan sponsor should enter the actual date on the material. The approval date should be the date that appears in HPMS with an approved status and the File & Use date should be the date the material is eligible for use in the market place (generally five (5) days after the piece is filed in HPMS). Refer to § 90.3.3 for additional guidance on deemed materials. These dates should appear on the material as they do in HPMS (i.e., include month, day and year). If the material is deemed approved, the plan sponsor will change the term "CMS Approved" to "Deemed" on its material master

copy/internal system and show the deemed date, which is obtained from HPMS. (For example, "H1234_0021 Deemed 03152010.") The plan sponsor does not resubmit the material in HPMS solely to include the CMS approval, File & Use or deemed date.

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

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2264(e), 423.2264(e)

Non-English or alternate *format* materials must be given a unique material ID. When submitting the materials, plan sponsors must utilize the proper dropdown menu in HPMS to designate that they are non-English versions. Refer to § 90.11 and the HPMS Marketing Module User Guide for further guidance.

NOTE: *The approval date for non-English materials should be the date that appears on the English version. The File & Use date for non-English material should be the date the English version is eligible for use in the market place (generally five (5) days after the piece is filed in HPMS).*

40.4 - Reference to Studies or Statistical Data

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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. *Plan sponsors should also disclose information on the relationship they have with the entity that conducted the study.* 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 *this information* in the *notes section when uploading the document that includes the reference into HPMS.*

- Plan sponsors may distribute a study or statistical data (for example, Medicare Prescription Drug Plan Finder information) to directly compare their plan to another plan in marketing materials to potential enrollees.
- If a plan sponsor uses study data that includes aggregate marketplace information on several other plans, it 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. Plan

sponsors are prohibited from using CMS, Medicare, or the Department of Health & Human Services (DHHS) logos, even when referencing a CMS study.

- Additional information may be requested by the Account Manager or CMS marketing reviewer to help in facilitate the review of submitted materials.

40.9 - Marketing to Beneficiaries of Non-Renewing Medicare Plans

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2264, 423.2264

Beneficiaries of non-renewing Medicare plans that have chosen not to renew their contracts *send the non-renewal letters to beneficiaries no later than October 2. If October 2 falls on a non-mail date then plan sponsors must ensure that the non-renewal letter is sent in advance to ensure that beneficiaries receive the non-renewal letter by the receipt date of October 2.*

CMS allows plan sponsors to market on October 1 (if they choose to do so) however; plan sponsors may not accept enrollment requests from beneficiaries of non-renewing Medicare plans without a valid election period in effect. Further information on appropriate election periods can be found in Section 30 of both Chapter 2 of the Medicare Managed Care Manual and Chapter 3 of the Medicare Prescription Drug Benefit Manual.

40.11 - Customer Service Call Center Hours of Operation

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.112(a)(7)(i) & (ii), 423.128(d)

A plan sponsor must list the hours of operation for its customer service call center in all places where a customer service number is provided for current and prospective enrollees to call (ID cards are excluded from this requirement). Refer to § 80.1 for additional guidance. The number must be a toll-free number. 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 (e.g., 24 hours a day/7 days a week).

40.11.1 – Agent/Broker Phone Number

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.112(a)(7)(i) & (ii), 423.128(d)

Materials that include an agent/broker's phone number should clearly indicate that calling the agent/broker number will direct an individual to a licensed insurance agent/broker. If an agent/broker phone number is listed, then the plan sponsor's customer service phone *and the TTY* number must also be included and all requirements regarding the customer service number in these Marketing Guidelines must be met (e.g., hours of operation, etc).

NOTE: *Business cards that include the agent/broker's phone number are not required to indicate on the card that calling the number will direct the individual to a licensed insurance agent/broker.*

40.12 - Use of TTY Numbers

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

Section 501 and Section 504 of the Rehabilitation Act

A TTY number must appear in conjunction with *the plan sponsors customer service number* 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 must 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 *advertisements*.

40.13 - Additional Materials Enclosed with Required Post Enrollment Materials

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.111, 423.128

Plan sponsors are permitted to enclose certain additional materials as part of required post-enrollment material mailings *as specified below. Unless specifically directed by CMS, or if the documents meet the criteria specified below, plan sponsors should not include additional documents with the ANOC and/or EOC mailings.* Any informational materials that are enclosed with post-enrollment mailings (*provider directory, pharmacy directory*) 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.

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.

40.14.6 - *Non-Benefit/Service-Providing Third Party Marketing Materials*

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2268, 423.2268

Non-benefit/service providing third party entities are organizations or individuals that supply non-benefit related information to Medicare beneficiaries or a plan sponsor's membership, which is paid for by the plan sponsor or the non-benefit/service-providing third party entity.

Example A: A company that promotes health and wellness and develops materials targeted to the Medicare population. CMS would not normally review materials created by health and wellness companies because plan sponsors are responsible for determining whether these materials meet the MMG requirements.

Example B: An individual that provides summaries of plan sponsors or highlights plans using CMS statistical data or other research data sources available to them and offers their services and/or materials to the plan sponsors. The plan sponsor would distribute or allow the non-benefit/servicing third party individual to distribute the materials to their plan membership and/or to prospective enrollee. CMS would not review materials created by the individual and plan sponsors are responsible for determining whether these materials meet the MMG requirements.

If a non-benefit/service-providing third party wishes to develop and/or provide information to a plan sponsor's members *and/or prospective enrollees*, it must submit its materials to the plan sponsor *who will ensure compliance with the MMG requirements and that the appropriate disclaimers are provided on the materials as provided in section § 50.1.13.*

Plan sponsors utilizing third parties for telephone calls to plan enrollees must adhere to all guidance in § 70.5.1.

40.15 - Providing Materials in Different Media Types

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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.

As such, a plan sponsor may elect to provide materials to members or prospective *enrollees* using a *different medium* other than traditional paper (i.e., *electronic or portable media* like e-mail, CD, DVD). With respect to materials that CMS deems mandatory (the SB, ANOC, EOC, the provider/pharmacy directory, Part D Explanation of Benefits, and the Model Part D Transition Letter), plan sponsors have the option of contacting members to determine *medium in which* 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, secure website) or via a recorded telephone conversation to determine whether they would like to receive a specific material or group of materials *using a different medium*. 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 *any* materials *using different media types* must:

- Provide hard copies of all member materials available to members upon request (Note that requests for hard copies of plan web pages are excluded from this requirement.)
- Ensure 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 *choice of media type* an election (opt-in) to receive plan communications *using that type*.
- 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 or choice *of media types* are undeliverable (for example an expired e-mail account).
- 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 *using media other than hard* copies (paper), the plan is *still* responsible for ensuring that it is in compliance with HIPAA.

40.16 - Standardization of Plan Name Type

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2268 (q), 423.2268 (q), section 1851 (a)(6) of the Act

Plan sponsors must include the plan type in each plan's name using standard terminology as developed by the Secretary. 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 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 plan sponsors, HPMS auto-populates the plan type label at the end of each plan name. 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, plan sponsors must display the plan type on all marketing materials, including plan logos. 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 type 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. CMS will allow plan sponsors to either spell out the plan name type or abbreviate on materials that are not generated from HPMS. For example, use of either “Acme Medicare HMO” or “Acme Medicare Health Maintenance Organization.”
- 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.
- Plans 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.
- Inclusion of the plan type is not required throughout an entire document. However plans must include the plan type on the front page or at the beginning of the document. Model documents to which the only modification is the addition of the required plan name type will still be eligible for a ten (10) day review provided no other modifications are made to the document.

NOTE: Since 2010, HPMS has automatically appended all plan names with the standardized plan type label, described below. Starting in 2011, the standardized plan type label will also distinguish which plans are Special Needs Plans (SNPs).

Please Note: Employer Group Waiver Plans (i.e., 800-series plans) will be appended with the standardized plan type labels below. There is no further distinction between 800-series plans and individual market plans.

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)
HMO SNP	Plan Name (HMO SNP)
PPO	Plan Name (PPO)
PPO SNP	Plan Name (PPO SNP)
HMO-POS	Plan Name (HMO-POS)
HMO-POS SNP	Plan Name (HMO-POS SNP)
ESRD II SNP	Plan Name (HMO-POS SNP)
PSO	Plan Name (PSO)
PSO SNP	Plan Name (PSO SNP)
MSA	Plan Name (MSA)
MSA Demo	Plan Name (MSA)
RFB PFFS	Plan Name (PFFS)
PFFS	Plan Name (PFFS)
ESRD I	Plan Name (PFFS)
1876 Cost	Plan Name (Cost)
1833 Cost	Plan Name (Cost)
PDP	Plan Name (PDP)
Regional PPO	Plan Name (Regional PPO)
Regional PPO SNP	Plan Name (Regional PPO SNP)
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)
CCRC SNP	Plan Name (HMO-POS SNP)

50.1 - Guidance and Disclaimers Applicable to Advertising Materials

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

Advertising materials generally contain less detail than explanatory marketing materials. Advertising materials may provide basic benefit information to entice a potential enrollee to request information. As a general rule, materials that contain basic benefit information are considered advertising. Although not an exhaustive listing, some examples of advertising materials include:

- Banner and banner-like ads; (*see exception as provided in § 50.1.2*)
- Direct mail;
- Counter tents;
- Event signage;
- Internet advertising; (*see exception as provided in § 50.1.2*)
- Outdoor advertising; (*see exception as provided in § 50.1.2*)
- Pharmacists' promotional buttons;
- Post stands;
- Print ads;
- Radio ads;
- Television ads; and (*see exception as provided in § 50.1.2*)
- Window stickers

The following disclaimers are applicable to advertising materials. It is the responsibility of the plan sponsor to ensure it meets all requirements contained within the referenced sections as well as any additional disclaimer requirements throughout § 50 related to specific materials or plan types (e.g., SNP, PFFS, invitations to events).

- Federal Contracting Statement – § 50.1.2
- Disclaimers When Benefits Are Mentioned (if applicable) – § 50.1.3
- Disclaimers for the Marketing of Educational Events (if applicable) – § 50.1.7
- Disclaimers on Advertisements and Invitations to Sales/Marketing (if applicable) – § 50.1.8
- Disclaimers on Advertising that Promotes a Nominal Gift (if applicable) – § 50.1.9
- Disclaimer for Third Party Marketing Materials (if applicable) – § 50.1.13

50.1.1 - Guidance and Disclaimers Applicable to Explanatory Materials

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2264, 423.2264

In general, explanatory marketing materials include those materials that are sent to prospective *enrollees* prior to enrolling (enrollment) and to current and new members as part of their enrollment (post-enrollment). Explanatory materials include a higher level of detail with regard to plan benefits and costs. As a general rule, materials that contain a high level of detail (such as premiums, cost-sharing, detailed plan brochure, *and multiple benefits*) are subject to all explanatory disclaimers and submission requirements.

The following disclaimers are applicable to explanatory materials. It is the responsibility of the plan sponsor to ensure they meet all requirements contained within the referenced sections as

well as any additional disclaimer requirements throughout § 50 related to specific materials or plan types (e.g., SNP, PFFS, PPO, and co-branding materials).

- Federal Contracting Statement – § 50.1.2
- Disclaimers When Benefits Are Mentioned – § 50.1.3
- Disclaimers on Materials that Mention Plan Benefit and Premium Information - § 50.1.4
- Information on Enrollment Limitations – § 50.1.5
- Availability *of Non-English Translations* – § 50.1.6

The bullets below outline additional disclaimers based on specific materials or plan types. They are included in this guidance as a reference tool for plans and reviewers but should not be considered an exhaustive list. It is the responsibility of the plan sponsor to ensure all disclaimers and requirements throughout § 50 are contained within the appropriate materials.

- Part D sponsors materials mentioning Part D benefits must also indicate: [“You may be able to get Extra Help to pay for your prescription drug premiums and costs. To see if you qualify for Extra Help, call: 1-800-MEDICARE (1800-633-4227). TTY users should call 1-877-486-2048, 24 hours a day/ 7 days 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 Medicaid Office (only required for pieces referencing Part D benefits or cost-sharing)]”. (§ 50.1.4)

***NOTE:** This language has been bracketed as optional language for those US territories in which the Extra Help Program does not apply.*

- MA and MA-PD plans must also insert: “Individuals must have both Part A and Part B to enroll.” (§ 50.1.5)
- Materials for marketing of education events must also include: “This event is only for educational purposes and no plan-specific benefits or details will be shared.” (§ 50.1.7)
- Invitations to sales/marketing events must also insert: “A *sales person* will be present with information and applications. For accommodation of persons with special needs at sales meetings, call <insert phone, TTY, and hours of operation>.” (§ 50.1.8)
- Materials promoting nominal gifts must also insert a written statement on all materials advertising/promoting drawings, prizes or any promise of a free gift that there is no obligation to enroll in the plan. (§ 50.1.9)
- Part D sponsor materials mentioning Part D benefits must also include a statement indicating that in general, beneficiaries must use network pharmacies to access their prescription drug benefit, except in non-routine circumstances, and quantity limitations and restrictions may apply. (§ 50.1.10)
- MA and MA-PD plans whose members are locked into a provider network must also insert information that the member must receive all routine care from plan providers. (§

50.1.11)

- Materials that are co-branded with providers must also insert “Other <pharmacies/physicians/providers> are available in our network.” (§ 50.1.12)
- Third-party materials must also include a disclaimer noting “Medicare has neither reviewed nor endorsed this information.” (§ 50.1.13)
- PPO plans must also insert information that it may cost more to get care from out-of-network providers, except in an emergency *or urgent care situation*. (§ 50.1.14)
- Section 1876 cost plans must insert information on premium and cost-sharing for services received through the plan and optional supplemental benefit packages. (§ 50.1.15)
- Non-network PFFS plans must also insert: “A Medicare Advantage Private Fee-for-Service plan works differently than a Medicare supplement plan. Your provider 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 provider does not agree to accept our payment terms and conditions of payment, they may choose not to provide health care services to you, except in emergencies. If this happens, you will need to find another provider that will accept our payment terms and conditions. Providers can find the plan’s terms and conditions on our website at: [insert link to PFFS terms and conditions].” If the material is part of an enrollment kit it must also contain a leaflet for provider education on plan rules and information. (§ 50.1.16)
- Full and partial network PFFS plans must also insert: “A Medicare Advantage Private Fee-for-Service plan works differently than a Medicare supplement plan. We have network providers (that is, providers who have signed contracts with our plan) for [[full network PFFS plan insert: all services covered under Original Medicare]][partial network PFFS plans should indicate the category or categories of services for which network providers are available]]. These providers have already agreed to see members of our plan. If your provider is not one of our network providers, then the provider 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 provider does not agree to accept our payment terms and conditions, they may choose not to provide health care services to you, except in emergencies. If this happens, you will need to find another provider that will accept our payment terms and conditions. Providers can find the plan’s terms and conditions on our website at: [insert link to PFFS terms and conditions].” If the material is part of *an* enrollment kit it must also contain a leaflet for provider education on plan rules and information. (§ 50.1.16)
- DE SNPs must also insert a statement that premiums, co-pays, co-insurance and deductibles may vary based on the level of help received. (§50.1.17)

- SNPs must also insert eligibility requirements for SNP enrollment (e.g., “This plan is available to anyone who meets the Skilled Nursing Facility (SNF) level of care and resides in a nursing home”) on enrollment explanatory materials. (§ 50.1.18)

50.1.2 - Federal Contracting Statement

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2264, 423.2264

All advertising and explanatory materials must include the statement that the plan sponsor contracts with the Federal government. Exceptions include:

- Banner and banner-like ads;
- Outdoor advertising; and
- Television and Internet banner ads

At least one of the following statements must be used by MA, MA-PD *or Cost* plans as the contracting statement. The statements should not be modified and may be either in the text of the piece or at the end/bottom of the piece.

- “A/An [insert plan type: HMO *plan*, PPO *plan*, PFFS *plan* POS plan, PSO *plan*] with a Medicare contract;”
- “A 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 *plan*, PPO *plan*, PFFS *plan*, POS plan, PSO *plan*, Cost *plan*, MSA *plan*];” or
- “A Coordinated Care plan with a Medicare Advantage contract.”
- “*A Coordinated Care plan with a Medicare Advantage contract and a contract with the [state] Medicaid program.*” *This disclaimer would be applied to all D-SNP marketing materials that have a contract with the state Medicaid program.*
- “*A Coordinated Care plan with a Medicare Advantage contract but **without** a contract with the [state] Medicaid program.*” *This disclaimer would be applied to all D-SNP marketing materials that do not have a contract with the state Medicaid program.*

NOTE: *All other SNP types should use the following disclaimer on their marketing materials – “A Coordinated Care plan with a Medicare Advantage contract.”*

PDP sponsors must use one of the following contracting statements below. The statements may not be modified and may either be in the text of the piece or at the end/bottom center of the piece.

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

50.1.4 - Explanatory Materials that Mention Plan Benefit and Premium Information

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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

Explanatory materials for all plan sponsors that *mention* benefit and plan premium information must:

- Include a disclaimer stating “You must continue to pay your Medicare Part B premium.” This disclaimer is not required if the Part B premium is entirely paid by rebates under the plan. This statement is required even if the plan premium is \$0. Note that full-benefit *Dual Eligible* SNPs for whose members the State pays the Part B premium should indicate that the Part B premium is covered for full-dual members.
- Indicate that limitations, copayments, and restrictions may apply.
- Part D sponsors must include the following in all explanatory materials that reference Part D premiums or other costs for Part D. Plans may include the following language in paragraph or bullet form if the plan sponsor is sending out an individual letter:

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

- 1-800-MEDICARE (1-800-633-4227). TTY users should call 1-877-486-2048, 24 hours a day/7 days 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, CMS encourages plans to insert the following on all enrollment materials that include Part D benefit and premium information:

“People with limited incomes may qualify for Extra Help to pay for their prescription drug costs. If *you qualify*, Medicare could pay for up *to seventy-five (75) percent or more* of *your* 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.”

50.1.5 - Information on Enrollment Limitations

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2264, 423.2264

Plans must indicate on all enrollment explanatory materials that members may enroll in a plan only during specific times of the year. Plans may either describe all enrollment periods in detail or refer individuals to the customer service department for more information. For example:

“Members may enroll in the plan only during specific times of the year. Contact <plan> for more information.”

Exception: Section 1876 cost plans not offering Part D benefits, DE SNPs, and Institutional SNPs (I-SNPs), should indicate that eligible beneficiaries can enroll at any time. Section 1876 cost plans should indicate that eligible beneficiaries can enroll at any time but may elect the Part D optional supplemental benefit, if offered, only during specific times of the year. Additionally MA and MA-PD plans must also include a statement on explanatory materials that individuals must have Part A and Part B to enroll in the plan.

50.1.6 - Availability of *Non-English Translations*

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2264, 423.2264

Plan sponsors *that meet the five percent (5) threshold for language translation (Refer to Section 30.8) must place the following alternate language disclaimer on all materials as noted in § 30.11, 30.12, 30.13 and the Part D Transition Letter.*

“This information is available for free in other languages. Please contact our customer service number at 1-800-XXX-XXXX” for additional information”.

The Alternate Language disclaimer should be placed in both English and all non-English languages that meet the five (5) percent threshold for the PBPs the document relates to. The non-English disclaimer should be placed below the English version and in the same font size as the English version. Plans must also include a phone number the beneficiary can call for the information in other language.

NOTE: ID cards are excluded from this requirement.

50.1.12 - Disclaimer for Materials that are Co-branded with Providers

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 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 explanatory marketing materials related to the members’ selection of specific providers or provider organizations (e.g.,

physicians, hospitals). Refer to § 30.3 for additional information on co-branding. Co-branding marketing materials are required to include the following disclaimer:

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

50.1.13 - Disclaimer When *Using* Third Party Marketing Materials

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2264, 423.2264

CMS does not review third party marketing materials developed by a third party entity which is not affiliated nor contracted with the plan sponsor. Plan sponsors choosing to provide marketing materials and/or services created by non-benefit/service-providing third-party entities must ensure that the following disclaimer is prominently displayed at the bottom center of the first page of the material or in the case of a website, on each page and is of a similar font size and style as the message:

“Medicare has neither reviewed nor endorsed this information.”

In addition, any marketing materials providing information on a subset of plan options and or services offered by a non-benefit/service providing third party entity must prominently display the following disclaimer on all materials. The disclaimer must also be included on each webpage that lists, compares, or names available plans in the service area.

“This is not a complete listing of plans available in your service area. For a complete listing please contact 1-800-MEDICARE or consult www.medicare.gov (TTY users should call 1-877-486-2048), 24 hours a day/7 days a week or consult www.medicare.gov.” This disclaimer must be prominently displayed on each material or, in the case of websites, on each webpage that lists, compares, or names available plans.

Plan sponsors are responsible for ensuring that non-benefit/service providing third party entities comply with all MMG requirements prior to distributing materials to its membership. For further details on what CMS considers a non-benefit/service providing third party entity, please refer to section 40.14.6.

50.1.20 - Television Advertisements

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2264, 423.2264

Television advertisements for a plan sponsor must include the plan sponsor’s toll-free number (*including TTY number*) and applicable requirements for hours of operation. Additionally, any television ads that mention benefit information must contain the general advertising disclaimer noted in § 50.1.3. 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. Television advertisements are File & Use documents.

50.1.22 Enrollment and Marketing Materials after Non-Renewal or Service Area Reduction (SAR) Notice to CMS

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.506

Enrollment and marketing materials must prominently announce to prospective enrollees the decision to non-renew or reduce the service area. For efficient operation of the program, plan sponsors that are non-renewing or reducing their service area should cease marketing of the non-renewed/reduced plan(s) after August 31st. The following is model language that may be used as an attachment or addendum or in a script for customer service representatives.

*“< Insert plan sponsor name> will [(not be renewing its Medicare contract) or (will not be serving the following areas) effective January 1, <Upcoming Year> or [will not be offering individual beneficiary coverage]. You may choose to enroll in our plan, but your coverage will automatically end on December 31, <Current Year>, (insert, if appropriate <areas plan sponsor will not be serving>). You are also entitled to enroll in a new MA-PD plan, section 1876 cost or PDP beginning **October 1, <current year> through January 31, <Upcoming Year>**. However, if you want your enrollment in the new plan to take effect on January 1, <upcoming year>, the new plan must receive your application by December 31st. You may also have the option of enrolling in a Medicare Cost Plan, if one is offered in your area. If you do not enroll in another MA-PD plan, Medicare Cost Plan or PDP plan by December 31, <current year>, you will be disenrolled from our plan and enrolled in Original Medicare on this date. You will receive additional information in the fall about your rights and additional options.”*

50.2 - Plan Sponsor Mailing Statements

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2272(b), 423.2272(b)

In order to ensure that beneficiaries can quickly and easily identify the contents of a plan sponsor’s mailing, all plan sponsors that mail information to prospective or current Medicare beneficiaries should prominently display one of the following four statements on the front of the envelope or the mailing itself (if no envelope is being sent). Plan sponsors are permitted to meet this requirement through the use of ink stamps or stickers if necessary, in lieu of pre-printed statements. Any delegated or sub-contracted entities and downstream entities that conduct mailings on behalf of a plan sponsor must comply with this requirement.

1. Advertising pieces – “This is an advertisement”
2. Plan information – “Important plan information”
3. Health and wellness information – “Health or wellness or prevention information”
4. Non-health or non-plan information - “Non-health or non-plan related information”

All mailings should include one of these four mailing statements. If a mailing is not advertising or a health and wellness mailing, but is related to an enrollee's plan, plan sponsors should categorize it as a plan information mailing. However, if the mailing contains non-health or non-plan related information (refer to § 170.2 for examples), a plan sponsor should use the "non-health or non-plan related information" mailing statement. Plan sponsors may not modify these mailing statements and must use them verbatim.

Mailing statements should only be placed on the mailing when no envelope accompanies the mailer (e.g., tri-fold brochure or postcard). Plan sponsors may place one of the four statements on the mailing so that they are visible from the window of the envelope (as opposed to on the outside of the envelope) only if the disclaimer is prominently displayed within the display window of the envelope and is separate and distinct from the beneficiary's name/address.

CMS expects that all plan envelopes or mailings will include one of the four statements and that the statements will be prominently displayed so that beneficiaries can easily identify the content of the mailer. In addition, plan sponsors must ensure that their plan name or logo is included in every mailing to *current and prospective enrollees* (either on the *front* envelope, *through the front window of the envelope*, or on the mailing when no envelope accompanies the mailer).

Plan sponsors should not create envelopes that look like they are being sent from an official government source (e.g., red, white & blue flags on the outside of the envelope or envelopes that are made to look like checks). The review and approval of envelopes with additional information other than the four mailing statements must be submitted for a forty-five (45) day review. If no other *information is included* with one of the four mailing statements, then envelopes may be submitted under the File & Use process.

CMS does not require resubmission of envelopes based only on a change in the envelope size. If a plan uses the same mailing statement on 3 different mailing packages (e.g., 8 x 12 envelope, letter size envelope, and box) the envelope with each mailing statement only needs to be submitted once, provided the required mailing statement remains unchanged and additional information is not included.

***NOTE:** Plan sponsors are not required to include the material ID on envelopes; however all envelopes must be submitted with an associated marketing material ID number.*

60.1 - Summary of Benefits (SB)

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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

The SB is the stand-alone pre-enrollment document used to inform prospective as well as existing enrollees of the benefits offered by the plan sponsor. The SB is a synopsis document and, therefore, is not intended to include benefit information in the same detail as the Evidence of Coverage. The information within the SB is standardized language to allow beneficiaries to more easily compare the benefits offered by different plan sponsors and includes the following sections:

- Section (I): The introduction and the beneficiary information section, which informs prospective *enrollees* of important aspects of enrolling in the plan. This section is standardized language that should not be modified except as indicated in the SB instructions.
- Section (II): The benefit comparison matrix, which is an output report of the plan sponsor's 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 standardized language that should not be modified except as indicated in the SB instructions.
- Section (III): 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 (IV): DE 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 (Medicaid);
 - A description of the benefits and cost-sharing protections that are covered under the DE SNP for dual-eligible individuals.

Plans sponsors are required to include the SB in their enrollment kits and must make the SB available upon request. Therefore, plan sponsors must create and submit an SB for CMS approval. DE SNPs must include the SB in their enrollment kit to fulfill the comprehensive written statement of benefit requirement.

Because the SB is a standardized document, CMS expects that the language for sections I and II will be identical to the SB report in HPMS. Any deviation from this language, outside of an approved hard copy change or global hard copy change, will result in CMS disapproval of the material. Deviations include, but are not limited to, insertion of footnotes, plan specific clarifications, or format alterations, except as indicated in the SB instructions. Plan sponsors should generate their SBs via HPMS.

SNPs should include the required comprehensive written statement in Section IV of the SB when submitting it to CMS for review. SNPs are responsible for ensuring the accuracy of the Medicaid benefits displayed in the SB by communicating with the States and/or utilizing State-specific materials. A template is available on HPMS for plans to use, and technical guidance on the Summary of Benefits can be found in Appendix 1.

If a plan sponsor's bid has been approved, CMS expects that plan sponsors will submit completed SBs to CMS for review. Plan sponsors should not submit SBs with unpopulated brackets for cost-sharing, benefits, etc., after the bid approval.

Plan sponsors 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 II of the benefit comparison matrix. Since the PBP will only print sections I and II of the SB for one plan, plan sponsors will have to create a side-by-side comparison matrix for two (or more) plans by manually combining the information into a chart format. Plan sponsors will also need to modify Section I of the introduction section to accurately reflect the plans that have been added to Section II 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.

Section 1876 cost plans must use the standardized SB if they intend to have a plan appear in the Medicare Options Compare and should refer to the SB for 1876 cost plans in Appendix 1. Instructions for use of SB template are provided in § 90.9.

60.2 - Part D ID Card Requirements

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 423.120(c)

All plan sponsors that offer Part D plans must provide a member identification card to a beneficiary no later than ten (10) calendar days from receipt of CMS confirmation of enrollment, or by the last day of the first month of enrollment, whichever occurs first. Plans should refer to the notification on *the* TRR that contains the earliest notification to identify the start of the ten (10) calendar day timeframe. 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.

MA-PD and section 1876 cost plans offering a Part D optional supplemental benefit may merge their medical and Part D ID cards 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 *is not* the SSN or Healthcare Insurance Claim Number (HICN) of the enrolled member.

Plans must include the CMS contract number and PBP number on the member ID card. ID cards may be printed using a font size equivalent to the NCPDP standard. ID cards are not required to include;

- *The marketing material identification number*
- *Hours of operation*
- *Disclaimers noted in § 50*

(Refer to § 30.3 regarding co-branding requirements related to ID cards.)

60.3 - ID Card Information for PPOs and PFFS Plans

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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*” 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.

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.

Refer to § 30.3 information regarding co-branding requirements related to ID cards and § 60.2 for Part D ID requirements.

60.4 - Directories

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 provider and/or pharmacy directories for their members and prospective *enrollees*. Plan sponsors must send a complete directory of providers/pharmacists to their members at the time of enrollment and annually, unless the plan sponsor uses change pages. If using the change pages, plan sponsors must send a complete directory of providers and/or pharmacists to their members at the time of enrollment and at least every three years from the enrollment date or from the date of the last mailing, whichever occurs first.

Plan sponsors (including section 1876 cost contractors) that have an Internet website must also post copies of their Evidence of Coverage, SB 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 available providers. *Employer/Union-only Group Waiver Plans (EGWP) must comply with both requirements, to mail provider directories and post directories on their plan website.*

Change pages constitute either the actual page being changed, or a list of changes with referenced pages. If a plan sponsor chooses to send change pages to members, the following requirements will also apply:

- Change pages should be issued when there is an update to the directory.
- Change pages must be dated.
- Change pages should be submitted for forty-five (45) day review.
- 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.

In instances where significant changes to the provider/pharmacy network occur, the organization must send a special mailing of change pages immediately. The requirement to send a special mailing for significant changes is in addition to all the other mailing timeframes. 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.

60.4.2 - Provider Directories

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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

MA, MA-PD, and section 1876 cost plans' provider directories must contain all information within the CMS model provider directory. Note that for DE SNPs, the Medicaid indicator in the provider directory is a required element for those plans that have a contract with the State Medicaid Agency. A provider directory that includes the Medicaid indicator will still qualify for a ten (10) day review. Plan sponsors are required to disclose all of the plan sponsor's contracted providers to each enrollee in *a* clear, accurate, and standardized form prior to the effective date of enrollment or within ten (10) calendar days of receipt of the enrollment confirmation and at least annually thereafter, the directory is provided to new members upon enrollment and current

members on an annual basis unless the plan sponsor uses change pages as outlined in § 60.4. MA, MA-PD and section 1876 cost plan sponsors that do not combine the model provider/pharmacy directories must list all Part B and Part D eligible contracted pharmacies in the provider directory.

Plan sponsors may indicate which of their participating physicians or physician practices support e-prescribing. Model directories that include e-prescribing information will still be considered a model document eligible for a ten (10) day review.

60.4.4 - Combined Provider/Pharmacy Directory

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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

MA-PD plans and section 1876 cost plans that offer prescription drug coverage may combine the model provider and model pharmacy directories in one document. If the plan sponsor chooses to use the two model directories without modification and combine them into one document, *the materials can be submitted either File & Use or for a ten (10) day review period per the rules articulated below:*

- Model provider and pharmacy directories used separately and without modification can be submitted File & Use.
- Model provider and pharmacy directories combined without any modification can be submitted File & Use.
- Model provider and pharmacy directories combined with the pharmacy section removed from the provider directory can be submitted for ten (10) day review.
- Model provider and pharmacy directories used separately or combined, and otherwise modified, must be submitted for forty-five (45) day review.

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

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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

With respect to the mailing of the directory at the time of enrollment and annually 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.) *Although individuals living in community residences like group homes or nursing facilities reside at the same residence, each individual must receive a copy of the directory.*

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.
- When mailing a directory to one address, the plan sponsor must include *the names of all those enrollees at that mailing address or they may list one name and include all others on the cover letter accompanying the directory.*
- If a member has previously elected to receive a provider directory *electronically, the plan sponsor may fulfill* the requirement *of mailing an annual directory through e-mail. Note that if the e-mail sent to members contains* a link to the plan sponsor's website (as opposed to an attachment with the directory), the e-mail must clearly direct the member to the location of the directory on the plan sponsors website.

60.5 - Formulary and Formulary Change Notice Requirements

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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

Part D sponsors must provide a list of drugs, *known as a formulary, to* enrollees at the time of enrollment and at least annually thereafter. Because CMS 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 (*See § 60.5.1*).

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:

- *Each* covered drug *must* display at the correct cost-sharing tier and with the approved utilization management edits (i.e., prior authorization, step therapy or quantity limits).
- *The* formulary drug category and class must also be consistent.
- *The* applicable HPMS approved formulary file submission ID *number* and version number *must be included. The* HPMS approved formulary file *submission ID* number *is* the HPMS formulary submission ID number of the approved formulary that is being marketed.

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 *the* Part D sponsor's 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. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 423.128

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

- Plan Name on cover page
- "<Year> Formulary (List of Covered Drugs)" on cover page
- "PLEASE READ: THIS DOCUMENT CONTAINS INFORMATION ABOUT THE DRUGS WE COVER IN THIS PLAN" on 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 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 sixty (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 (UM):** Part D plans must indicate any applicable UM tools (e.g., prior authorization, step therapy, and quantity limit restrictions) for the drug. A description of the indicator used to describe the UM 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).

- 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).

60.5.3 - Changes to Printed Formularies

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 423.128(a)-(c)

Beneficiaries have a legitimate expectation that they will have access to the 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 formulary changes via errata sheets mailed to affected members. While Part D sponsors retain the flexibility to utilize other processes for notifying beneficiaries of non-maintenance changes to their printed formularies, CMS expects Part D sponsors to send out errata sheets with formulary changes no less than monthly to the extent that any negative formulary changes have occurred and that affected members will receive a hard copy of such changes (website updates alone will not suffice). *Errata sheets must include a statement explaining that the plan will continue to cover the drugs in question for enrollees taking the drug at the time of change for the remainder of the plan year as long as the drug continues to be medically necessary and prescribed by the member’s physician and was not removed for safety reasons. Refer to the Prescription Drug Manual, Chapter 6, Sections 30.3.3.3 and 30.3.4.1.* 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.

60.6 - Part D Explanation of Benefits

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 true out of pocket (TrOOP)-eligible amounts.
- A notice of the enrollee's right to request an itemized statement. The EOB should contain sufficient information necessary for the beneficiary to understand their prescription drug coverage and benefits. However, to the extent a beneficiary requests additional items not already addressed in the EOB, a plan must provide this information.
- 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.
 - 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).
- *An EOB does not need to be generated by the plan sponsor when retroactive changes apply to prior benefit year prescription fills. For example, a plan's final EOB for CY 2010 must be sent in January 2011, for December 2010 fills. Once the final EOB for CY 2010 has been sent, sponsors are not required to send an EOB for any retroactive adjustments for prior benefit year fills (prescription fills made prior to December 31, 2010).*
- Notice regarding formulary changes to affected enrollees, as provided in 42 CFR 423.120(b)(5) and in § 60.5. *This includes changes to the list of excluded drugs on the plan's marketed formulary.*

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. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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

With the exception of fully integrated DE SNPs, section 1876 cost plans not offering Part D and employer/union group plans, plan sponsors must ensure their current members receive the ANOC and EOC, *their LIS riders and abridged or comprehensive formularies for the upcoming coverage year* no later *than September 30th* of each year. New Enrollees with an effective date of November 1st or December 1st should receive both an EOC for the current contract year and an ANOC/EOC for the upcoming contract year. Additionally, plan sponsors must send new enrollees with an effective date of January 1st or later a standalone EOC for that contract year.

In the instances listed above where plan sponsors are sending the standalone EOC, the document may be edited to remove all references to the ANOC. In addition, plan sponsors doing so do not need to resubmit the standalone EOC under a new code provided they have previously submitted a combined ANOC/EOC in HPMS.

Regardless of the effective date, the document must be provided to all new enrollees no later than ten (10) calendar days from receipt of CMS confirmation of enrollment or by the last day of the first month of enrollment, whichever occurs first. Plan sponsors should refer to the notification on the TRR that contains the earliest notification to identify the start of the ten (10) calendar day timeframe.

DE SNPs may separate the ANOC from the EOC, but must send the ANOC *for the upcoming coverage year* to current members by *September 30th* and send the EOC to enrollees by December 31st. Beneficiaries of employer/union group plans must receive their ANOC and EOCs no later than fifteen (15) days before the beginning of the employer/union sponsor's open enrollment period (refer to § 20.3.2.1.2 of Chapter 9 of the Medicare Managed Care Manual and § 20.3.2.1.2 of Chapter 12 of the Prescription Drug Benefit Manual).

Section 1876 cost plans offering Part D benefits must send the combined standardized ANOC/EOC to their enrollees *by September 30th* of each year. Section 1876 cost plans that do not offer Part D benefits must send the combined ANOC/EOC by December 1 of each year.

To ensure that plan sponsors are mailing their ANOC/EOC timely, plan sponsors must indicate the actual mail date in HPMS within three (3) days of mailing. Plan sponsors that mail in waves should enter the actual date of the last wave. For instructions on meeting this requirement, refer to the update material section of the Marketing Module- User Guides in HPMS.

Plan sponsors must use the standardized ANOC/EOC errata model to correct any errors. Plan sponsors are expected to submit the errata model for review via HPMS. Although the ANOC/EOC errata model is standardized, it is not eligible for File & Use submission. The ANOC/EOC errata document must be submitted under code 1030 and is subject to a ten (10)-day prospective review.

Plan sponsors that elect to revise, correct and resend updated corrected ANOC/EOC to beneficiaries rather than simply sending enrollees the errata model document must attach the standardized errata model document to the front of the corrected ANOC/EOC. CMS expects that current versions of ANOC/EOC will be available on the website. If a plan issues an errata for an ANOC/EOC they must ensure the most up-to-date, corrected version is placed on the website.

If there are any changes or corrections to materials (for example, the benefit or cost-sharing information differs from that in the approved bid) the plan sponsor will be required to correct those materials for prospective enrollees and send errata sheets/addenda/reprints to current members by a reasonable timeframe. In cases where non-compliance is discovered, the plan sponsor may be subject to penalties including intermediate sanctions and civil money penalties.

60.8 - Mid-Year Changes Requiring Enrollee Notification

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.111(d)(3)

Mid-year benefit enhancements are no longer permitted. However, if a national coverage determination takes effect mid-year, and is covered under the contract, or is covered on a fee-for-service basis outside the contract, but the plan sponsor chooses to offer coverage to beneficiaries; such services may be added mid-year. *All National Coverage Determinations (NCDs) are effective on the date the decision memorandum is released (the same as the date it is posted to the National Coverage Analysis page of the Medicare Coverage Center website at http://www.cms.gov/mcd/index_list.asp?list_type=nca). The MAO is required to notify all enrollees of the new coverage or change in coverage of the item or service within 30 days of the release of the date of the NCD, regardless of whether the NCD is covered under the PBP or will be covered by original Medicare for the remainder of the contract year.*

Additionally, if the newly covered service is covered outside the contract, the enrollee must be told that he or she could receive this service from any Medicare provider, including out-of-network Medicare providers. The plan sponsor may use a variety of mechanisms to inform enrollees of the change in coverage. At a minimum, the MAO must provide notice on the plan website within 30 days, with subsequent publication in the next plan newsletter or other mass mailing not specifically dedicated to the NCD notification. Alternatively, MAOs may choose to provide this information to enrollees in a targeted way, such as via email or one-time mailings specific to this issue.

In the case of a *non-NCD related* change to plan rules during a contract year (note that these rule changes must be positive for enrollees relative to the rules articulated in the plan sponsor's post enrollment material, the plan sponsor must notify CMS and obtain its approval and must also notify enrollees at least thirty (30) days before the effective date of the change. The plan sponsor may use a variety of mechanisms to inform enrollees of the mid-year change, including one-time mailings, newsletters and other vehicles.

For more information on application of Medicare coverage policies to Medicare Advantage, see Chapter 4, section 80 (National and local coverage determinations), of this manual, at <http://www.cms.gov/manuals/downloads/mc86c04.pdf>.

70.1 - General Guidance about Promotional Activities

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2268, 423.2268

Promotional activities (including provider promotional activities) must comply with all relevant Federal and State laws. Plan sponsors may be subject to compliance and/or enforcement actions if they offer or give 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 *designed to promote or encourage a beneficiary to enroll in a plan*. 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.

Any promotional activities or items offered by plan sponsors *to prospective or current members*, including those that will be used to encourage retention of members:

- Must be of nominal value (refer to § 70.2 for additional information on nominal value);
- Must be offered to all people eligible to enroll without discrimination;
- **Must not** be offered in the form of cash or other monetary rebates;
- **May not** be items that are considered a health benefit (e.g., a free checkup);
- **May not** consist of lowering or waiving co-pays should the person enroll;
- **May not** be used *or included with the SB, ANOC/EOC*;
- **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 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);and
- **May not** be tied directly or indirectly to the provision of any other covered item or service.

➤ *As discussed in § 110, plans may provide Value Added Items and Services (VAIS), such as pass through discounts, to their current enrollees provided the plan complies with all requirements. Since the plan incurs no cost (except truly administrative costs) in providing the VAIS, the market value of the VAIS has no limit. However, if the plan links the VAIS to appreciation for the plan – e.g., the plan when notifying current enrollee’s states that the VAIS is done in appreciation for joining the plan – then VAIS must be treated as a promotional item. In particular, the market value of the VAIS must comply with the nominal value requirements described in § 70.2.*

70.1.2 - General Guidance about Rewards and Incentives

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2268, 423.2268

Plan sponsors may only offer rewards and incentives to plan enrollees to promote one of the following target activities:

- Welcome to Medicare” visit (includes a referral for an ultrasound screening for abdominal aortic aneurysm for eligible beneficiaries)
- *Adult Wellness visit*
- *Any combination of the following adult Immunization – influenza, pneumococcal and Hepatitis B vaccination- In other words, a plan may target for a reward and incentive all three enumerated adult immunizations or they may chose to target for a reward and incentive only one or two of the adult immunizations*
- 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
- Smoking Cessation
- HIV screening for high risk groups

To qualify for a reward the target item must be offered in whole as defined above – for example, a plan may not reward current enrollees just for annual blood pressure readings vs. the entire annual wellness visit. The reward items given to plan enrollees for doing any of the above target activities are subject to the following requirements:

- Each reward item must have a retail value monetary cap not to exceed \$15 per item; *additionally the aggregate retail value of all reward items offered annually may not exceed* \$50 in the aggregate on an annual basis per member per year;
- Must be offered to all *current* eligible members without discrimination;
- **Must not** be offered in the form of cash or other monetary rebates;
- **May not** be items that are considered a health benefit (e.g., a free checkup);
- **May not** consist of lowering or waiving co-pays;
- **May not** be used in pre-enrollment advertising, marketing, or promotion of the **plan**;
- **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 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
- Are subject to disclosure requirements – that is, the plan must clearly inform the enrollee what target activities are rewarded, what limitations, if any, apply, and how to claim the reward items; 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. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 promotional 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 rules also apply to rewards and incentives. The definition of nominal value is slightly different for a pre-enrollment promotional gift and a post enrollment reward.

To satisfy the requirements of meeting nominal value for rewards to current enrollees:

- Each individual item *must be* worth \$15 or less, based on the retail value of the item.
- *The annual aggregate value of all items offered by the plan to each person must be \$50 or less, based on the retail value of the items.*

To satisfy the requirements of meeting nominal value for pre-enrollment promotional items:

- *Each individual item must be worth \$15 or less, based on the retail value of the item;*

The following additional rules must be followed when providing gifts of a nominal value whether pre- or post –enrollment:

- 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.
- Cash gifts are prohibited *even if their worth is less than \$15. Cash gifts* include charitable contributions made on behalf of potential enrollees and *those* gift certificates and gift cards that can be readily converted to cash, regardless of dollar amount.

NOTE: 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) 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. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2268(p), 423.2268(p)

Plan sponsors **may not** provide meals, (or have meals subsidized) *to prospective enrollees at sales/marketing events* (any event or meeting at which plan benefits are being discussed and/or plan materials are being distributed). *Refer to § 70.7 for guidance regarding education events.*

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 the event meets CMS’ strict definition of an educational event, and complies with the nominal gift requirement in § 70.2. Meals are not allowed at sales/marketing events. Refer to § 70.7 for guidance regarding 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 bite size dessert items
- Crackers
- Muffins
- Cheese
- Chips
- Yogurt
- Nuts

It is the responsibility of plan sponsors to monitor the *activities* of all agents selling their plan(s) and *ensure that they are complying with this requirement*. Oversight activities conducted by CMS will verify that plan sponsors and *their* agents are complying with this provision. *Enforcement actions will be taken against plan sponsors as necessary.*

70.3 - Unsolicited E-mail Policy

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 MA, PDP, or section 1876 cost plans.
- Plan sponsors may not e-mail prospective *enrollees at* e-mail addresses obtained through friends or referrals.
- Plan sponsors must provide an opt-out process for beneficiaries who no longer wish to receive e-mail communications.

70.4 - Marketing through Unsolicited Contacts

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 including leaving information such as a leaflet, flyer, or door hanger *at a residence*, or leaving information such as a leaflet or flyer on someone’s car.
- Approaching beneficiaries in common areas (e.g., parking lots, hallways, lobbies, *sidewalks*, etc.)
- Telephonic or electronic solicitation including leaving electronic voicemail messages, text messaging, or *sending unsolicited* e-mail *messages*.

NOTE: Agents/brokers who have a pre-scheduled appointment which becomes a “no-show” may leave information at the no-show beneficiary’s residence.

The prohibition on marketing through unsolicited contacts does not extend to mail and other print media (*e.g., advertisements, direct mail*) provided they are constructed and approved in accordance with the information set forth in these Medicare Marketing Guidelines. Leads may still be generated through mailings, websites, advertising and public sales events. Refer to § 70.3 regarding email policy.

Plan sponsors 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 Medicare 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 (*BRC*) used for documenting beneficiary agreement for a contact must be submitted to CMS for review/approval. *Additionally, plan sponsors that develop a BRC should include a statement on the BRC that by replying to this card, a sales person may call you.*

70.5 - Specific Guidance on Telephonic Contact

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 *restriction on unsolicited contact*. *CMS makes a distinction between contact with beneficiaries to establish a new relationship with a plan sponsor or independent sales agent, and contact that is with a plan member or a beneficiary where a business relationship already exists (e.g., the agent has sold the beneficiary non-Medicare products in the past).*

When contacting beneficiaries to establish new relationships, a consent for future contact must be limited in scope, short-term, and event-specific. The consent to contact may not be treated as open-ended permission for future contacts. However, for agents contacting their own clients, or plan sponsors (or contracted agents) contacting their current members, consent for each specific contact is not required to discuss plan business.

NOTE: All plans sponsors must comply with § 170 regarding the use of beneficiary data as related to telephonic contact. Also refer to § 80.1.9 for information about *telephonic* script review and approval.

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

- *Making* unsolicited outbound calls to beneficiaries *about other business as a means of generating leads for Medicare plans* (Examples of *other lines of business* include, but are not limited to: a discount prescription drug card, a Medigap plan, a needs assessment, an educational event, *or* a review of Medicare coverage options, or any other service or product that is not an MA plan or PDP.)
- *Calls to beneficiaries based on referrals* resulting in an unsolicited contact. (e.g., *referrals from friends, relatives, neighbors, or companies that collect, buy, or sell contact information*). *If an individual would like to refer a friend or relative to an agent or plan sponsor, the agent or plan sponsor may provide contact information such as a business card that the individual may give to the friend or family member.* In all cases, a referred beneficiary needs to contact the plan or agent/broker directly. A call from an agent *or plan sponsor* to a beneficiary who was referred would be considered an unsolicited contact.

- 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 to beneficiaries who attended a sales event, unless the beneficiary gave express permission at the event for a follow-up call (including a completed scope of appointment form).
- 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. However, plan sponsors may not conduct unsolicited calls to their Medigap enrollees regarding their, MA, Part D or section 1876 cost plan products.
- *Contact members to promote other plan types (i.e., plans may contact their PDP members to promote their MAPD offerings) and discuss plan benefits.*
- *Contact their members to discuss educational events.*
- *Contact their* 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 *BRC* or asking a customer service representative (CSR) to have an agent contact them. This permission applies only to the entity from which the beneficiary requested contact, for the duration of that transaction,

for the scope of product (e.g., MA-PD plan or PDP) previously discussed or indicated in the reply card.

- Return beneficiary phone calls or messages, as these are not unsolicited.
- Contact *their* members via an automated telephone notification to inform them about general information such as the AEP dates, availability of flu shots, upcoming plan changes and other important information.

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 *representing a Medicare health plan* is subject to the CMS marketing requirements at any point *in which* a discussion with a beneficiary *turns to Medicare health plans*, even if during *the* sale of an unrelated product, such as long-term care insurance. (See scope of appointment guidance in § 70.9.1)

Finally, for those outbound calls (refer to § 70.4, 70.6, and 80) that are allowable under these Medicare Marketing Guidelines, plan sponsors must comply to the extent applicable with 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

All outbound scripts utilized by the plan sponsor or its contractors must be submitted for review and approval prior to being used in the marketplace. *Please refer to § 80-Special Guidance on Telephonic Activities and Scripts for additional guidance on outbound calls.*

70.5.1 - Specific Guidance on Third-party Contact

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2268(d), 423.2268(d)

Plan sponsor representatives (*and other third-parties*) are prohibited 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 marketing calls to beneficiaries (other than to current plan members *or to an agent’s existing clientele*)

- Unsolicited calls to beneficiaries for *other business* (for example, a “benefits compare” meeting) and providing those contacts to plans for ultimate use in an MA or PDP sales appointment.

Independent 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 client, the agent is not required to set up an appointment to discuss other available plans/products with the beneficiary.*
- *Initiate a phone call to confirm an appointment that has already been agreed to by a beneficiary via a completed scope of appointment form.*

Sales of *Medicare health plan 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.

If during the course of an outbound call by a Medigap issuer the beneficiary requests additional information on a MA or PDP product, at this time a discussion can be held on the MA or PDP product, as long as the call is being recorded.

*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.*
- *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.*

70.6 - Outbound Enrollment and Verification Calls to all New Enrollees

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2272(b), 423.2272(b)

All plan sponsors are required to conduct outbound enrollment and verification (OEV) calls for enrollments effectuated by agents and brokers – including both independent and employed agents and brokers - to ensure individuals requesting enrollment understand the plan rules. It is important for the plan sponsor’s sales staff to obtain from the applicant the best phone number to

be used for verification and to provide a description of the enrollment verification process to the applicant during the application process.

OEV calls must be made to the applicant after the sale has occurred; they cannot be made at the point of sale. The plan sponsor must ensure that the verification calls are not conducted by sales agents and that sales agents are not physically present with the applicant at the time of the verification call. Plan sponsors may not use automated calling technologies to effectuate these outbound calls; *our expectation is that calls may be* interactive. The plan sponsor must conduct these calls for all enrollment requests generated by agents and brokers (including both independent and employed agents and brokers). Excluded from this requirement are enrollments into employer or union sponsored plans, enrollments into PACE plans, enrollments submitted to plan sponsors by qualified State Pharmaceutical Assistance programs (SPAPs), and auto-enrollments, facilitated enrollments, and reassignments effectuated by CMS. Please note that if an individual with LIS makes an enrollment request that supersedes or changes a CMS-generated enrollment, and that election is effectuated by an agent or broker, the outbound verification requirements apply.

Plan-to-plan switches within an MA or Part D parent organization (both contract-to-contract and within contract) require outbound enrollment verification if the enrollment request involves a change in plan type or plan product (e.g., HMO to PPO, SNP HMO to non-SNP HMO). Plan-to-plan switches within an MA or Part D parent organization involving the same plan type or product type (e.g., PFFS to PFFS, DE SNP to DE SNP, PDP to PDP) are not subject to OEV requirements.

Plan sponsors may continue to use existing scripts provided that they convey the information included in the most up-to-date model script. New or revised scripts must be submitted to CMS through the normal process for approval.

We expect plan sponsors to make a minimum of three documented attempts to contact the applicant by telephone within fifteen (15) calendar days of receiving the enrollment request. If the enrollment application is received incomplete, we expect plan sponsors to concurrently conduct the outbound verification calls while obtaining completed information for the application. Plan sponsors that are unable to successfully complete the outbound verification on the first attempt, we expect the sponsor to send the applicant an enrollment verification letter.

Plan sponsors must not delay processing the enrollment request (including, but not limited to, activation of benefits and submission of enrollment request data to CMS) while completing the OEV process. If the sponsor makes a determination to deny an enrollment request prior to completing the OEV process, the sponsor must discontinue the OEV process. If the sponsor receives a TRR from CMS rejecting the enrollment prior to completing the OEV process, the sponsor must suspend the OEV process and will resume the OEV process if the sponsor determines the reject to be erroneous, such that the enrollment will be resubmitted to CMS

Plan sponsors must send the enrollee the enrollment verification letter in addition to any other required enrollment notice, such as enrollment acknowledgement and confirmation letters. After the model enrollment verification letter has been sent, the plan sponsor is expected to make and document at least two additional telephone attempts to successfully complete the outbound

*enrollment verification. The minimum three attempts to conduct the verification by telephone and, if applicable, the mailing of the enrollment verification letter, are expected to be completed no later than **fifteen (15) calendar days** of the plan sponsor's receipt of the enrollment request. Plan sponsors must document outbound enrollment verification activities. We expect that both the script and the enrollment verification letter will inform beneficiaries that they must notify the plan sponsor of their intent to cancel the processing of their enrollment within seven (7) calendar days from the date of the letter or call or the last day of the month in which the enrollment request was received, whichever is later. For AEP enrollment requests, the script and the enrollment verification letter will inform beneficiaries that they must notify the plan sponsor of their intent to cancel the processing of their enrollment within seven (7) calendar days from the date of the letter or call or by December 7, whichever is later.*

The outbound verification requirements apply to sales agents and other plan representatives only when they are acting in the role of sales agents and as such, are steering beneficiaries to one or a subset of all available plans. In other words, if a licensed agent is acting strictly as a customer service representative – that is, carrying out customer service duties such as providing factual information, or taking demographic information in order to complete an enrollment request at the initiative of an enrollee who has already decided to enroll in a plan – the outbound enrollment verification requirements do not apply. However, if there is steering and/or marketing by the CSR/agent and an enrollment request results, such an enrollment request is subject to the OEV requirements.

A model outbound enrollment verification call script *and letter* is available at http://www.cms.hhs.gov/ManagedCareMarketing/09_MarketngModelsStandardDocumentsandEducationalMaterial.asp#TopOfPage.

70.7 - Educational Events

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2268(1), 423.2268(1)

Educational events are *events designed to inform Medicare beneficiaries about MA, Prescription Drug or other Medicare programs, but do not steer, or attempt to steer potential enrollees toward a specific plan or limited number of plans.* Educational events may not include any sales activities such as the distribution of marketing materials or the distribution or collection of plan applications. *Educational events must be explicitly advertised as “educational,” otherwise they will be considered by CMS as sales/marketing events. Educational events are held in public venues and do not extend to in-home or one-on-one settings.*

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 and activities by plan sponsors or their representatives at an educational event:

- *Any materials designed to inform potential enrollees about MA or other Medicare programs, but do not steer, or attempt to steer, potential enrollees toward a plan or a 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 and consistent with CMS' definition of nominal gift.
- A business card if the beneficiary requests information on how to contact the plan or agent for additional information, as long as the business card is free of plan marketing or benefit information.
- Meals may be provided as described in § 70.2.1.
- Plan sponsors may participate in educational health fairs and health promotional events as either a sole sponsor or co-sponsor of an event hosted by multiple organizations as long as the event does not include a sales presentation and is billed as educational. *NOTE: Plan sponsors that intend to market at these events should not refer to the event as educational and must comply with the requirements in section § 70.8.*
- Respond to questions asked at an educational event. A response by plan sponsor's representative to questions will not render the event as sales/marketing provided *that the scope of the response does not go beyond the question asked and no enrollment forms are neither distributed, nor* accepted.

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, enrollment 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.
- *Solicit prospective beneficiaries for individual appointments under the premise that the appointment is for educational purposes.*

The following are examples of events that are *not educational*, and are therefore subject to all guidance noted in § 70.8:

- 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 a marketing/sales event. A plan sponsor may not advertise an educational event and then have a marketing/sales 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 *or senior citizen center* 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.
- *A plan sponsor participates in a health fair or health promotion event and distributes plan specific materials including enrollment applications.*

70.8 - Marketing/Sales Events

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2268, 423.2268

Marketing/sales events are *events designed to steer, or attempt to steer, potential enrollees toward a plan or limited set of plans. At marketing/sales events, plan representatives may discuss plan specific information like premium, cost-sharing, or benefits and/or distribute or collect applications. All one-on-one appointments with Medicare beneficiaries are considered by CMS as sales/marketing events (See also §70.9). However, one-on-one appointments are not entered into the marketing events module.*

There are two main types of marketing/sales events – formal and informal. 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 *may have been* invited to attend.

Informal marketing/sales events are *conducted with* a less structured presentation or *in a less formal* environment. They typically utilize a table, kiosk *or a recreational vehicle (RV) that is* manned by a plan sponsor representative who can discuss the merits of the plan's products.

NOTE: *If an event is scheduled as a marketing/sales event then requirements for marketing/sales events must be met, even if only one person is in attendance at the event.*

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 (*See §40.14*).

At marketing/sales events plan sponsors ***may:***

- *Discuss plan specific information (e.g., premiums, cost-sharing or benefits).*
- Distribute health plan brochures and enrollment materials.
- Accept and perform enrollments.
- Formally present benefit information to the audience via a scripted talk, electronic slides, handouts, etc.
- Provide a scope of appointment form for a subsequent meeting; if a beneficiary requests a one-on-one meeting then the beneficiary must fill out a scope of appointment.
- Provide educational content to the audience or passersby.
- Provide a nominal gift to attendees with no obligation. Note that the value of any give-away, including entertainment, must be consistent with CMS' definition of nominal gift.
- Contribute cash towards prize money to a foundation or another entity if the event is jointly sponsored. The plan cannot claim to be the sole donor of the prize and it must be clear that the prize is attached to the event and not the individual organization.

NOTE: *Plan sponsors that distribute enrollment applications during a sales event must provide the information in §30.11, required materials in the enrollment kit.*

At marketing/sales events, plan sponsors ***must:***

- Announce all products/plan types that will be covered during the presentation at the beginning of that presentation (e.g., HMO, PFFS, MSA, etc).

- Submit all sales scripts and presentations for approval to CMS prior to their use during the marketing/sales event (see § 80 for additional information).
- Clearly read or state the following disclaimer during PFFS presentations/events:
 - For non-network PFFS plans: “A Medicare Advantage Private Fee-for-Service plan works differently than a Medicare supplement plan. Your provider is not required to agree to accept the plan’s terms and conditions of payment, and thus may choose not to treat you, with the exception of emergencies. If your provider does not agree to accept our terms and conditions of payment, they may choose not to provide health care services to you, except in emergencies. If this happens, you will need to find another provider that will accept our terms and conditions of payment. Providers can find the plan’s terms and conditions of payment on our website at: [insert link to PFFS terms and conditions of payment].”
 - For full and partial network PFFS plans: “A Medicare Advantage Private Fee-for-Service plan works differently than a Medicare supplement plan. We have network providers (that is, providers who have signed contracts with our plan) for [[full network PFFS plan insert: all services covered under Original Medicare]][partial network PFFS plans should indicate the category or categories of services for which network providers are available]]. These providers have already agreed to see members of our plan. If your provider is not one of our network providers, then the provider is not required to agree to accept the plan’s terms and conditions of payment, and thus may choose not to treat you, with the exception of emergencies. If your provider does not agree to accept our terms and conditions of payment, they may choose not to provide health care services to you, except in emergencies. If this happens, you will need to find another provider that will accept our terms and conditions of payment. Providers can find the plan’s terms and conditions of payment on our website at: [insert link to PFFS terms and conditions of payment].”
- Clearly explain the following during SNP presentations/events:
 - Eligibility limitations (e.g., required special needs status)
 - Special enrollment period (SEP) to enroll in, change or leave SNPs
 - Process for *in*voluntary disenrollment if the beneficiary loses his/her Medicaid or institutional status (or becomes ineligible for the C-SNP)
 - A description of how drug coverage works with your plan.

At a marketing/sales 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.
- Provide meals to attendees (refer to § 70.2.1 on exclusion of meals).
- Require beneficiaries to provide any contact information as a prerequisite for attending the event. *This includes requiring an email address or any other contact information as a condition to RSVP for an event online or through mail.* Plans should clearly indicate on any sign-in sheets that completion of any contact information is optional.
- Plans sponsors may not ask beneficiaries to provide personal contact information in order to participate in a raffle or drawing. Plan sponsors should use other mechanisms (e.g., raffle tickets, random numbers) for conducting the drawings.
- Use prohibited statements at marketing/sales event (as stated in these Medicare Marketing Guidelines).
- *Solicit enrollment applications prior to the start of the AEP.*

70.8.1 – Notifying CMS of Scheduled Marketing Events

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2268, 423.2268

Plan sponsors must upload all *formal and informal* marketing/sales events *via HPMS* prior to advertising the event *or seven (7) calendar days* prior to the event’s scheduled date, *whichever is earlier*. For detailed instructions, *including the earliest upload date*, please refer to the “Marketing Events” section in the user guide of the HPMS Marketing module. Note that EGHP events that are only for EGHP members should be excluded from entry in HPMS.

CMS recognizes that plans sponsor may have last minute events scheduled. CMS will permit these events to be uploaded into HPMS. However, CMS’ expectations are that at least 90% of all formal and informal events will be uploaded at least seven (7) calendar days prior to the event’s scheduled date. Failure to adhere to a 90% upload requirement may result in a compliance action.

In the Event Name field, plan sponsors should begin each Event Name field entry with either one of the following, followed by the actual event name:

- Informal
- Formal
- Educational

For example, “Informal: *store kiosk*”

Changes to marketing/sales events (e.g. cancellations, changes of room and other updates and edits) *should be updated in HPMS as soon as possible but* must be updated in HPMS at least forty-eight (48) hours prior to the scheduled event.

Cancellations - Notification of cancelled sales events should be made, whenever possible, more than forty-eight (48) hours prior to the originally scheduled date and time of the event. 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 *less than* forty-eight (48) hours before its originally scheduled date and time, the plan sponsor must:
 - Notify its Regional Office Account Manager of the cancellation and cancel the event in HPMS.
 - Ensure a representative of the plan sponsor is 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. The representative should remain on site at least 15 minutes after the scheduled start of the event. If the event was cancelled due to inclement weather, a representative is not required to be present at the site.
2. If a sales event is cancelled more than forty-eight (48) hours before the originally scheduled date and time, the plan sponsor must *cancel the event in HPMS, must notify the Regional Office Account Manager, and must* notify beneficiaries of the cancellation by the same means the plan sponsor used to advertise the event. *If beneficiaries are notified of a cancellation more than forty-eight (48) hours before the event, then there is no expectation that a representative of the plan sponsor will be present at the site of 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 the newspaper's production and/or distribution schedule prohibits timely notification, the plan sponsor must provide evidence to the respective Account Manager (newspaper guidelines with submission timelines, run dates, etc.).
- 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.
- If an announcement of the sales event was sent through a mass mailing, then the plan sponsor should consult with the Regional Office *Account Manager* to

decide upon the most reasonable way to notify beneficiaries about the event cancellation.

70.9 - Personal/Individual Marketing Appointments

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2268, 423.2268

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. *Appointments must follow the scope of appointment guidance (See §70.9.1).*

At these appointments, the *plan sponsor's representative* may:

- Distribute plan materials (*CMS* encourages plan sponsors to provide the *enrollment kit at one-on-one* appointments),
- *Inform beneficiaries* on how to *get plan information* (e.g., mail, website, *customer service*).
- Discuss various plan *options*.
- Provide educational content.
- *Distribute or* collect enrollment forms

The plan sponsor's representative **may not** do the following:

- Discuss plan options that were NOT agreed to by the Medicare beneficiary (see scope of appointment information in § 70.9.1).
- Market non-health care related products (such as annuities, life insurance or VAIS.)
- Ask a beneficiary for referrals.
- Solicit/accept an enrollment request (application) for a January 1st effective date prior to the start of the Annual Enrollment Period (AEP) unless the beneficiary is entitled to a Special Election Period (SEP) or *is* within their initial coverage election period/initial enrollment period.

70.9.1 - Scope of Appointment

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

422.2268(g) and (h), 423.2268 (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 MA, and PDP products.

The scope of appointment must be agreed to by the Medicare beneficiary prior to any personal/individual marketing appointment. Agents and brokers can document the scope of

appointment in writing via a scope of appointment form. If the scope of appointment is being documented by recording a phone call in advance of the appointment, the call should be placed by the plan sponsor and not the agent/broker. The sales person is bound to only discuss during that appointment 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. Upon CMS request, the plan sponsor must be able to produce documentation.

To further clarify the requirements around 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. 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. However, CMS expects plans to record and maintain documentation on why it was not feasible to obtain the scope of appointment prior to the 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) *cannot agree to the scope of appointment on behalf of the beneficiary but can confirm the appointment. See § 70.5.1-Specific Guidance on Third Party Telephonic Contact.*
- 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, and e-mail, etc.
- A beneficiary may sign a scope of appointment form at a marketing/*sales event* for a *future* appointment. In these instances, the forty-eight (48) hour waiting period does not apply. For example, if a beneficiary attends a marketing presentation, and, after 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 § 70.8 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 is posted at http://www.cms.hhs.gov/ManagedCareMarketing/09_MarketngModelsStandardDocumentsandEducationalMaterial.asp#TopOfPage). Written scope of appointment forms must be submitted in HPMS under Category 4000, Code 4011. We encourage plan sponsors to use our model scope of appointment form. Use of the model without modification may be submitted under File & Use. A modified form must be submitted for forty-five (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.

70.10.2 - Guidance for Dual Eligible Outreach Program

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 – including any contracted entity conducting outreach on behalf of the plan sponsor – must adhere to the following guidance.

Plan sponsors and their contracted entities conducting outreach on their behalf must:

- Ensure that all outreach materials meet all applicable Medicare Advantage Marketing Guidelines requirements that apply to materials outside the dual eligible outreach category as described throughout this guidance.
- 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, information regarding Medicaid status is needed to confirm eligibility for a DE SNP.
- 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 that Medicaid status will be needed to confirm eligibility for a DE 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 *TTY* 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' 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.
- Communicate directly with stakeholders (e.g., SHIPs, State Agency) to ensure better education and preparation prior to the outreach initiation process.

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 six 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.
- Subcontract all outreach efforts to another entity or entities. In such cases, while the plan sponsor retains all responsibility for meeting CMS’ requirements, and must submit all documentation to the appropriate CMS Regional Office for approval per the submission guidance provided later in this section.

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.
- 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.

70.10.3 - Outreach Submission Requirements *for Dual Eligibility*

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262, 423.2262

In general, plan sponsors either develop and conduct their own outreach or contract with an external entity to provide the expertise, materials, and member assistance. Regardless of the approach, plan sponsors must submit the following information to their Regional Office Account Manager.

In electronic format, using the US Postal Service or other delivery method;

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. Internal training programs the organization is using to educate staff involved in outreach.
6. An internal plan for protecting the confidentiality of the member's financial or other personal information gathered in the outreach process.
7. Outreach letters and other materials (e.g., brochures, Authorization to Represent form) going to plan sponsor members.
8. 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.

In some instances, a plan sponsor may choose to submit an outreach proposal that CMS has already approved for use by another plan sponsor or an outreach proposal that will be used by other plan sponsors in the future. This is common when a plan sponsor is part of a national organization with multiple contracts, each of which is conducting its own outreach but sharing the same outreach materials. This is also common when a plan sponsor conducts its own outreach efforts through a subcontracting entity that provides the same services and outreach materials to multiple plan sponsors.

If a 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 the plan sponsor must submit an attestation from either itself or its contracted outreach vendor stating: (1) that the proposal has

been approved by CMS, (2) the date of that approval, and (3) that the new submission does not contain substantive changes to the approved program.

70.10.4 - CMS Review/Approval of Outreach Process *for Dual Eligibility*

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 detailed in § 70.10.5.

70.10.5 - Reviewing New Outreach Programs *for Dual Eligibility*

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 forty-five (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 additional State(s) that impact another CMS Regional Office, then the Regional Office Account Manager who received the request 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.

70.10.6 - Reviewing Previously Approved Outreach Programs *for Dual Eligibility*

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 ten (10) day time frame CMS has established for reviewing standardized marketing materials. CMS' 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 Manager for review according to the review process above.

70.12 - Marketing Guidance for the Provider Setting

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 its sub-contractors, including but not limited to, pharmacists, pharmacies, physicians, hospitals, and long-term care facilities.

These Medicare Marketing 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 these guidelines.

70.12.1 - Plan Activities and Materials in the Health Care Setting

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 or are waiting 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 in health care settings extends to activities planned in health care settings outside of normal business hours.

Only upon request by the beneficiary are plan sponsors permitted to schedule appointments with beneficiaries residing in long-term care facilities (including nursing homes, assisted living facilities, board and care homes, etc.). 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. CMS does not expect providers to proactively contact all participating plans; rather, if a provider agrees to make available and /or distribute plan marketing materials they should do so knowing they must accept future requests from other plan sponsors with which they participate. Providers are also permitted to display posters or other materials in common areas within the long-term care facility and in admission packets announcing all plan contractual relationships. Long term care facility staff are permitted to provide residents that meet the I-SNP criteria an explanatory brochure for each I-SNP with which the facility contracts. The brochure can explain about the qualification criteria and the benefits of being enrolled in an I-SNP. The brochure may have a reply card or telephone number for the resident or responsible party to call to agree to a meeting or request additional information.

70.12.2 - Provider-Based Activities

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 downstream providers or agents) with the plan sponsor comply with the requirements outlined in this chapter.

The plan sponsor must ensure that any providers contracted (including 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 patient.

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 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.

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 and Chapter 3 of the Medicare Prescription Drug Benefit 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 plans or PDPs.*
- *Making phone calls or directing, urging or attempting to persuade beneficiaries to enroll in a specific plan based on financial or any other interests of the provider.*
- *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 is a prohibited marketing activity.*
- *Accepting compensation directly or indirectly from the plan for beneficiary enrollment activities.*
- *Distribute materials/applications within an exam room setting.*

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 § 70.12.3) for additional information on affiliation.)*
- *Provide information and assistance in applying for the LIS.*
- *Make available and/or distribute plan marketing materials including provider affiliation materials for a subset of contracted plans only as long as providers offer the option of making available and/or distributing marketing materials from all plans with which they participate. CMS does not expect providers to proactively contact all participating plans to solicit the distribution of their marketing materials: rather, if a provider agrees to make available and/or distribute plan marketing materials for some of its contracted plans, it should do so knowing it must accept future requests from other plan sponsors with which it participates. To that end, providers are permitted to:*
 - *Provide objective information on plan sponsors' specific plan formularies, based on a particular patient's medications and health care needs.*

- *Provide objective information regarding plan sponsors' plans, including information such as covered benefits, cost sharing, and utilization management tools.*
- *Make available and/or distribute PDP enrollment applications, but not MA or MA-PD enrollment applications, for all plans with which the provider participates.*
- *Refer their patients to other sources of information, such as SHIPs, plan marketing representatives, their State Medicaid Office, local Social Security Office, CMS' website at <http://www.medicare.gov/> or 1-800-MEDICARE.*
- *Print out and share information with patients from CMS' 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 Medicare Prescription Drug Plan Finder information via a computer terminal for access by beneficiaries. Plan sponsors should advise contracted providers of the provisions of these rules.

70.12.3 - Provider Affiliation Information

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2268, 423.2268

Providers may announce new affiliations and repeat affiliation announcements for specific plan sponsors through general advertising (e.g. radio, television). New affiliation announcements are those providers that have entered into a new contractual relationship with the plan sponsor. Providers may make new affiliation announcements within the first 30 days of the new contract agreement. 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, e-mail, or phone. Additional direct mail and/or e-mail communications from providers to their patients regarding affiliations must include all plans 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 plan sponsors, 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 does not require CMS approval.

70.12.4 - SNP Provider Affiliation Information

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2268, 423.2268

Providers may feature SNPs in a mailing announcing an ongoing affiliation. This mailing may highlight the provider's 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 SNPs with which the provider is affiliated.

70.12.5 - Comparative and Descriptive Plan Information

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 (refer to § 90.2 for more information on submission of marketing materials).

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

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 (e.g. SHIPs, State agency or independent research organizations that conduct studies). For more information on non-benefit/service providing third party providers, refer to § 40.14.6.

70.12.7 - Providers/Provider Group Websites

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2268, 423.2268

Provider websites 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 applicable to certain plan types such as section 1876 cost plans, Medicare MSAs, 800-series employer group waiver plans, and Religious Fraternal Benefit plans. SNPs may use the links, and the SNP should notify the provider that they may use the OEC link if they choose to but that it is not required.*

80.1 - Customer Service Call Center Requirements

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.111(g)(1), 423.128(d)(1)

From October 15 to *February 14*), all plan sponsors are required to operate a toll-free call center for both current and prospective enrollees that operates seven (7) 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 live customer service representative.

From *February 15*, until the following annual enrollment period, plan sponsors are still required to operate a toll free call center for both current and prospective enrollees that operates from 8:00 A.M. to 8:00 P.M. *Monday through Friday*. During this *time period on* Saturdays, Sundays, and holidays, plan sponsors are permitted to use alternative technologies to meet the customer service call center requirements. 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, no more than one business day later.

Call centers must meet the following operating standards:

- Provide information in response to inquiries outlined in § 80.1.3.
- Follow an explicitly defined process for handling customer complaints.
- Provide *interpreter* service to all non-English speaking, *limited English proficient (LEP)* and hearing impaired beneficiaries.
- Average hold time must not exceed two (2) minutes. The average hold time is defined as the average time spent on hold by a caller following an interactive voice response (IVR) *or touch tone response* system and before reaching a live person.
- Eighty (80) percent of incoming calls must be answered within thirty (30) seconds.
- Disconnect rate of all incoming calls must not exceed five (5) percent.

80.1.1 - Pharmacy Technical Help Call Center Requirements

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 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 twenty-four (24) hour pharmacies must operate their pharmacy technical help call centers twenty-four (24) hours a day as well.

The pharmacy technical help call center must meet the following operating standards:

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

80.1.3 - Required Scripts for Inbound Informational Calls

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 Medicare Marketing Guidelines. Refer to § 170 for more information about allowable uses of beneficiary information that is applicable to § 80.1.3-80.1.5.

At a minimum, plans must develop scripts to respond to prospective and current 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.

- *Make information about Best Available Evidence (BAE) policy available for those who contact the plan sponsor's call center. Refer to § 100.2 for additional information that*

must be made available either in writing or over the phone, in the event the plan sponsor is contacted.

- Request for pre-enrollment information *
- Request for post-enrollment information inquiries on:*
 - Benefits*
 - 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, processing and payment*
 - Formulary transition process*
 - How to access the Part D grievance, coverage determination (including exceptions) and appeals process*
 - How to obtain extra help
 - Current TROOP status
 - How to obtain needed forms
 - How to replace a member identification card
 - Service area

NOTE: Telephone enrollment scripts are not considered "Informational Inbound Scripts" rather they are discussed in § 80.1.6.

80.1.4 - Requirements for Inbound Informational Scripts

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

Inbound informational scripts must be submitted for review and approval as an entire script, talking points, or bullet points. If scripts are submitted as talking or bullet points, the material must clearly *differentiate* acceptable language and practices from prohibited language and practices.

Inbound information scripts 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 Medicare Marketing Guidelines that is appropriate to the purpose of the script (e.g., all relevant disclaimers outlined in § 50).
- Include a privacy statement clarifying that the beneficiary is not required *to provide any health related information to the plan representative unless it will be used to determine enrollment eligibility.*
- 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.
- 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 (refer to § 70.4 regarding unsolicited contact for more information).
- If applicable, any references to a VAIS benefit must use the appropriate disclaimer located in § 110.
- Always close by offering to send follow-up materials (published information) for inbound informational calls. Directing callers to the website is optional.
- Include a greeting that can be delivered by either a CSR or Interactive Voice Response (IVR).
 - Clearly state the plan name, the name of the programs being represented, and a brief description of the plan (e.g., an MA-PD plan, MA plan, section 1876 cost plan or PDP). 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 may 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”).

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 call.

80.1.6 - Requirements for Enrollment Scripts/Calls

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 (note that the guidance regarding inappropriate transfer of calls as noted in § 80.1.5 still applies). Telephone enrollment scripts and processes must follow the guidance provided in § 40.1.3 of Chapter 2 of the Medicare Managed Care Manual and § 40.1.3 of Chapter 3 of the Medicare Prescription Drug Benefit Manual.

Telephone enrollment scripts must be submitted in their entirety for review and approval. *The telephone enrollment scripts* must clearly *differentiate* acceptable language and practices from prohibited language and practices. In developing and submitting scripts for enrollment via inbound calls, plan sponsors must:

- Clearly state 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 § 40.1.3 of Chapter 2 of the Medicare Managed Care Manual and § 40.1.3 of the Medicare Prescription Drug Benefit Manual.
- *Provide confirmation of having accepted the telephone enrollment request, such as a confirmation tracking number or other tracking mechanism.*
- Although not part of the telephone enrollment request, plan sponsor may close the call with:

- A summary of the plan into which the individual has requested enrollment;
- A statement that the individual will receive a notice acknowledging *receipt of the enrollment – e.g., acknowledging* request for additional information *or denial of enrollment (e.g. not eligible)*;
- Contact information for questions including toll-free telephone and TTY numbers.

NOTE: Enrollment scripts may not be submitted as talking or bullet points.

80.1.7 - Prohibited Activities for Enrollments Scripts/Calls

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.60 (c), 423.32 (b)

Plan sponsors **are not** permitted to:

- Conduct outbound telephone enrollment except as required to perform outbound education and verification calls (refer to § 70.6)
- Transfer outbound calls to inbound lines for telephone enrollment;
- Market or enroll other lines of business as part of the telephone enrollment script; and
- Request or collect credit card numbers or bank account information for any purpose during the telephone enrollment call.

80.1.8 - Requirements for Telephone Sales Scripts (Inbound or Outbound)

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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

Any telephone sales scripts (inbound or out-bound) must be submitted verbatim (talking or bullet points are unacceptable) however plans are asked/encouraged to include commonly asked questions in talking points or bullet points to CMS for review. Plan sponsors should incorporate all required disclaimers as provided in § 50, as well as all other relevant requirements as outlined in these Medicare Marketing Guidelines. For outbound scripts, plan sponsors must pay close attention to the guidance on marketing through unsolicited contacts in § 70.4 and 70.5 on specific telephone contact. This guidance extends to all downstream contractors.

Inbound calls made directly to a sales department or sales agent must clearly inform the beneficiary if/when the nature of the call moves from a sales presentation to telephonic enrollment. This must be done with the full and active concurrence of the Medicare beneficiary, ideally with a yes/ no question.

When conducting outbound sales calls:

- Scripts must include a privacy statement clarifying that the beneficiary *is not required to provide any health related information to the plan representative unless it will be used to determine enrollment eligibility.*
- Plan sponsors are prohibited from requesting beneficiary identification numbers (e.g. Social Security Numbers, bank account numbers, credit card numbers, HICNs) but in limited circumstances may inquire about an individual's special needs status to determine the appropriateness of enrollment in a SNP.

80.1.9 - Requirements for All Other Inbound/Outbound Scripts

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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

The following guidance applies to all scripts that do not fall into the categories previously addressed (inbound informational calls, enrollment scripts, or inbound/outbound telephone sales calls).

- Scripts must include a privacy statement clarifying that the beneficiary is not required to provide any *health related information to the plan representative unless it will be used to determine enrollment eligibility.*
 - Outbound auto-dialings that are informational in nature will not be required to include this disclaimer in their scripts.
 - Plan sponsors are prohibited from requesting beneficiary identification numbers (e.g. Social Security Numbers, bank account numbers, credit card numbers, HICNs). This policy does not extend to calls to existing members to conduct normal business related to enrollment in the plan (e.g., CTM complaint resolution). Note that in limited circumstances, plans may inquire about an individual's special needs status to determine the appropriateness of enrollment in a SNP.
 - Plan sponsors must say they are contracted with Medicare to provide prescription drug benefits or that they are a Medicare approved MA-PD plan, MA-only plan, section 1876 cost plan (with or without Part D benefits), or PDP.
 - Plan sponsors cannot use language in scripts that imply they are endorsed by Medicare, calling on behalf of Medicare, or that Medicare asked them to call the member.

Plan sponsors must incorporate in their scripts all applicable disclaimers as noted in § 50, as well as all other relevant requirements outlined in these Medicare Marketing Guidelines (e.g., hours of operation, TTY number, etc.).

90 - Guidance on the Marketing Review Process

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

422.2262, 423.2262

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' marketing review process is detailed in this section.

90.1 - Plan Sponsor Responsibilities

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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. Plan sponsors are responsible for conducting a quality check prior to submitting all materials for review to CMS. Generally, MA, MA-PD, and section 1876 cost plan sponsors should not submit current contract year marketing materials for CMS review and approval after June 30th of that contract year. Note that this date does not apply to File & Use materials.

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).

90.2.1 - Ad-Hoc Enrollee Communications Submission

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2260 (5)(vii), (6), 422.2262 (d), 423.2260 (5)(vii) ,(6), 423.2262(d)

In our efforts to streamline the review and approval of the beneficiary communications to current members, ad-hoc enrollee communications – as defined in § 20 – will not be considered marketing materials. However, CMS has the authority to review ad hoc enrollee communications, and, upon review, to determine that these communications may no longer be used. CMS has created an HPMS code [7013] for submission of ad hoc enrollee communications. These materials will be submitted File & Use. CMS reserves the right to retrospectively review such materials to ensure that the information being conveyed to enrollees is accurate and not misleading. Plan sponsors with concerns about whether a material fits the very narrow definition of an ad hoc enrollee communication should contact their Regional Office Account Managers or Marketing Reviewer.

NOTE: *Ad-Hoc enrollee communications must include the following disclaimer to ensure beneficiaries have access to translator services: “If you need help understanding the information in this [letter], please contact customer service at 1-800-XXX-XXXX for free language translator services”.*

90.5 - Time Frames for Marketing Review

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262(a) 423.2262(a)

With the exception of those materials that qualify for File & Use (as outlined in § 90.6.1), or the materials identified in § 90.2.1, plan sponsors may not distribute or otherwise make available to eligible beneficiaries any marketing materials unless such materials have been submitted to CMS and CMS has rendered a status of approved or deemed. The marketing review time period begins on the date of a marketing material’s submission to HPMS.

90.5.1 - 45-Day Standard Review Period

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 forty-five (45) calendar days in which to render a review decision. If, on the forty-sixth (46th) day, a decision has not been rendered by CMS, the material will be “deemed approved.”

The forty-five (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 thirty-second (32nd) day CMS renders the decision of disapproved, upon correcting the material’s deficiencies and resubmitting the piece, the forty-five (45) day clock starts anew.

The forty-five (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.

90.6.1 - Materials Qualified for the File & Use Submission

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262(b), 423.2262(b)

The following materials are qualified for the File & Use *process*, provided they are used without modification and the plan sponsor has submitted a File & Use certification to CMS:

- Provider directory (including combined provider directory and pharmacy directory);
- Standardized combined ANOC/EOC;
- Pharmacy directories;
- Abridged and comprehensive formularies;
- Certain CMS enrollment/disenrollment letters; and
- Certain claims, grievance, organization/coverage determinations (including exceptions), and appeals model letters.
- OMB-approved forms

File & Use submissions for direct mail and general advertising materials may be allowed provided the materials are not explanatory marketing materials that mention benefit and plan premium information as stated in § 50.1.4.

Materials that are not eligible for File & Use submission are direct mail and general advertising materials that are explanatory marketing materials that mention benefit and plan premium information as described in § 50.1.4.

The HPMS Marketing Module identifies those materials that qualify for File & Use under the material code look-up functionality.

NOTE: If a plan sponsor (s) does not have File & Use certification, they are considered ineligible to submit documents as File & Use. In this instance, any such submissions would be subject to compliance actions.

90.6.2 - Materials Not Qualified for File & Use Submission

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262(b), 423.2262(b)

Materials that do not qualify for File & Use are those that pose greater risk to a Medicare beneficiary if they are inaccurate in any way. These documents include but are not limited to:

- SB;
- Member Handbook;
- Member ID card;
- Enrollment forms;
- Disenrollment forms;

- Errata sheets.

In addition, explanatory marketing materials as defined in § 50.1.4, unless expressly identified by CMS as qualified for the File & Use processes, must be submitted for either a forty-five (45) or ten (10) day review process as provided in HPMS.

90.6.4 - Loss of File & Use Certification Privileges

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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;
- Fails to file two or more materials at least five (5) calendar days prior to distribution or publication; or
- Is found after a targeted review by CMS, to consistently submit a large number of File & Use materials through a forty-five (45) day review process, or to consistently submit through the File & Use process materials that do not meet the requirements of these Medicare Marketing Guidelines.

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.

Following are the certification procedures for Part D sponsors:

- 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 five (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.

Following are the certification procedures for MA, MA-PD, and section 1876 Cost Plans:

- Each plan sponsor should submit the File & Use Certification marketing materials to CMS at least five (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 (refer to Model File & Use Certification form, Appendix 3). The requirement for submission of a signed certification form is a one-time only requirement, and the signed certification 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 its appropriate CMS Regional Office. The File & Use certification form (see Appendix 3) states that the plan sponsor agrees that all advertising materials and model documents that are used are accurate, truthful and not misleading.
- 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 they are electronically submitted through HPMS); and 4) all materials include the plan *sponsor's* contract number (*e.g.*, H####, R####, S#### or MCE identifier of Y####) as a prefix to the marketing materials identification number.

90.7.1 - Standardized Language

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262 (c), 423.2262 (c)

Standardized language refers to language developed by CMS or other Federal agencies (e.g., Office of Management and Budget (OMB) approved forms) which is mandatory for use by plan sponsors and cannot be modified *in a substantive or material way*. Impermissible modifications *generally* include altering the content or language in any way *or altering the format in a way that is not consistent with the form or manual instructions*. For OMB-approved forms submitted as File & Use refer to § 90.6.1.

90.7.2 - Required Use of Standardized Model Materials

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262 (c) , 423.2262 (c)

Standardized model materials are model documents that a plan must utilize without modification. In instances where CMS provides a standardized model document, plan sponsors must use the document without altering the text or its order. Unless otherwise directed, the only allowable alterations to standardized models include populating variable fields, correcting grammatical errors, adding the plan name/logo and adding the CMS marketing material identification number.

Standardized models differ from non-standardized model materials in that standardized models are mandatory for use by plan sponsors as written. Conversely, plan sponsors may or may not use non-standardized model documents (see § 90.7.3). When utilizing a standard model material, plan sponsors must remove any reference to the words “exhibit”, “model”, or “appendix” contained within the title of the model document (note that the title of the standardized model should remain). For CY2012, standardized model materials that are mandatory for use by plans include:

- Summary of Benefits
- Annual Notice of Change/Evidence of Coverage
- *Errata ANOC/EOC*
- *Plan Ratings*

90.7.3 - Model Materials

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262 (c), 423.2262 (c)

For certain materials, CMS has developed model documents that are available for use by the plan sponsor. The use of CMS model documents is optional unless otherwise directed by CMS or if the material falls into the category of standardized model materials (refer to § 90.7.2). *Plan sponsors that choose to modify the model language other than populating variable fields must ensure that all elements provided in the model are included in the non-model document.*

Generally, model documents used without modification will result in a ten (10) day marketing review period *or may be submitted via File & Use as specified in § 90.6.1*. Model documents modified by the plan sponsor will result in a forty-five (45) day review period.

The following modifications to CMS model materials will still render the material allowable for use under the ten (10) day review period; populating variable fields, correcting grammatical errors, *changing the font*, adding the plan name/logo, and adding the CMS marketing material identification number. Unless otherwise required, plans may choose to retain the title of the model document or modify the title to make it more beneficiary friendly. Note that any reference to the words “exhibit,” “model,” or “appendix” contained within the title of the model document must be removed. Any other modifications made to the document will make the material subject to the standard forty-five (45) day review process and/or ineligible for File & Use submission.

It is important to note that materials found to be non-model yet uploaded by the plans sponsors for model review will be disapproved. *Repeated* submission of non-model materials as models or submission of models inappropriately coded as used without modification will be viewed as a compliance issue.

To facilitate reviews, plan sponsors should indicate the model/exhibit title and applicable CMS chapter/manual or HPMS memorandum date in the comments section of HPMS whenever a model document is submitted. If the document is an attachment to a CMS issued memorandum, the plan sponsor should *indicate* the subject and the date CMS issued the HPMS memorandum.

CMS expects that the final versions of a model document will be submitted. Any models submitted with brackets and variable fields should be submitted via the template process (see § *90.8 and § 90.10 for additional information*).

90.8 - Template Materials

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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. *CMS classifies template materials as either standard templates or static templates. Plan sponsors must submit the final populated version of standard templates in HPMS. Static templates include placeholders that are exempt from being submitted once populated.*

Utilizing template materials allows a plan sponsor to submit one “master document.” *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.* Examples of variable elements include date and location information for sales presentations, benefits that may vary between plans, cost sharing, premium and plan sponsor names.

90.8.1-Standard Templates

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262, 423.2262

A standard template is a marketing material that includes placeholders for variable data to be populated and resubmitted in HPMS at a later time. For standard templates, plan sponsors must submit the final material that has been populated, (in the placeholders) with plan specific information. Plan sponsors are required to indicate the “master document” is a template when submitting the material in HPMS (see 90.10 for additional information).

90.8.2-Static Templates

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262, 423.2262

A static template is a marketing material that includes placeholders for variable data that are excluded from being resubmitted in HPMS once populated. To meet the criteria for a static template, ALL variable data within the material must be exempt from being resubmitted in HPMS as noted below. For static templates, plan sponsors should not indicate the “master document” is a template when submitting the material in HPMS (see § 90.10. for additional information).

The following variable placeholders are excluded from the population requirement:

- *Dates;*
- *Events;*
- *Addresses, phone or fax numbers;*
- *Hours of operation;*
- *Organization or company names;*
- *Plan name;*
- *Logos;*
- *Agent/Agency;*
- *Persons’ names and pronoun variations;*
- *URLs;*
- *Member specific variables (i.e., case numbers, drug specific references and coverage determination decisions); and*
- *Co-branding information*

Materials with any other variable placeholders, including those for plan specific benefits, premium, and cost-sharing information must be submitted through the standard template process and finalized by uploading the “Final Expedited Review/Populated Template” in HPMS.

90.9 - Submission for Summary of Benefits Submitted as a Template Prior to Bid Approval

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262, 423.2262

To ensure plan sponsors are able to submit information efficiently and with minimal burden, CMS allows plan sponsors to create and submit an SB prior to bid approval. Should plan sponsors choose to exercise this option, they may submit an SB with variable placeholders around plan benefits and cost-sharing information. These materials should be submitted as templates and populated after bid approval. These populated materials will not need to be resubmitted to the appropriate CMS Regional Office *reviewer* for additional *review* prior to use. *However*, plan sponsors must submit each variation of the template through HPMS as a populated template within thirty (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 materials to reflect the changes.

If a plan sponsor chooses to submit a SB for review with no section III, no comprehensive written statement of benefits (section IV), and no hard copy changes, *the SB* will be treated as a standardized document and reviewed using the ten (10) day timeframe. However, if the plan

sponsor chooses to submit the SB with section III and/or section IV it will be reviewed within the forty-five (45) day time period. Model documents used as templates may not be modified.

Plan sponsors should not submit SBs with variable placeholders around plan benefits and cost-sharing after bids have been approved; rather, these SBs should be submitted as final documents.

90.10 - Submission of All Templates

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262, 423.2262

Template material or model template materials must be uploaded to CMS through the HPMS marketing module and 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 the 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.

If a material meets all requirements for static templates (as outlined in 90.8.2), plan sponsors should not indicate the material is a template when uploading the material in HPMS. Static templates may be submitted in this manner given that CMS does not require populated versions of static templates be uploaded at a later date.

Conversely, if a material meets requirements for standard templates (as outlined in 90.8.1), plan sponsors must indicate the material is a template when uploading the material in HPMS. Standard templates require that plan sponsors submit the final template material that has been populated (in the placeholders) with plan specific information.

When submitting a material with variable placeholders in the HPMS, plan sponsors should indicate that the material is a standard template when initially submitting the piece by checking the "Template Material" field, and entering a "Template Material ID" as required. Plan sponsors should submit standard templates using current material codes and categories that define a piece.

Templates must be populated within 30 days of the approved date, thirty (30) days of the File & Use distribution date, or thirty (30) days of the approved bid for materials filed prior to bid approval. Plan sponsors are responsible for submitting final versions of templates in the HPMS Marketing Module using the associated "Final Expedited Review" code, and will be required to enter the "Template Material ID" of the original "MASTER" template material in the "Template Material ID" field.

Changes to previously approved non-variable text in the template must be submitted for review and approval by CMS. 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).

If there are any changes or corrections to materials (for example, the benefit or cost-sharing information differs from that in the approved bid) the plan sponsor will be required to correct those materials for prospective *enrollees* and send errata sheets/addenda/reprints to current members by a reasonable timeframe. 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.

90.11 - Submission of Non-English (*Alternate Formats) Materials

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2264 (e), 423.2264(e)

CMS requires that plan sponsors make marketing materials available in any language that is the primary language of more than *five* percent of a plan's PBP service area. In addition, enrollee information (as identified in § 30.9) must be made available to the visually impaired upon request.

“*Alternate Formats” materials must be based on previously approved English versions of the same material.

NOTE: Non-English marketing materials submitted by plan sponsors must attest to the completeness and accuracy of the material through an electronic attestation in HPMS. CMS expects that when plan sponsors complete the electronic attestation in HPMS, they are attesting that any translated or alternate format versions are identical in content to the English material.

Plan sponsors that submit Non-English (*Alternate Formats) materials must designate the material as “*Alternate Formats” in HPMS using the following process during data entry:

1. The material must be given a unique Material ID.
2. The user must 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.) ***NOTE: The approval date for non-English materials should be the date that appears on the English version. The File & Use date for non-English material should be the date the English version is eligible for use in the market place (generally five (5) days after the piece is filed in HPMS).***
4. The submitted “*Alternate Formats” material will receive a Material Status of “Alternate Formats”.

Materials submitted as an alternate format material may be used immediately.

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 its attestations at a later date, it 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.

Plan sponsors *use of alternative formats materials*, will be subject to verification monitoring review and associated penalties for violation of CMS policy *as discussed in § 30.8*. 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.

Plan sponsors will be allowed to submit “*Alternate Format materials” once the original English version of the material submission is complete. Users will be allowed to upload multiple alternate format files for contracts and for plan benefit packages. If a plan sponsor allows online enrollment through the plan sponsor’s secure website, the online enrollment mechanism does not need to be available in “*Alternate Format” materials. However, in addition to other requirements (refer to § 100 for details), the online enrollment mechanism must indicate that “Alternate Format” materials are available by contacting the plan sponsor directly.

90.13 - Submissions Outside of HPMS

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262, 423.2262

Under extraordinary circumstances, and with prior *approval* 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 *receives* materials.

90.15 - Multi-Contract Entities (MCEs)

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262, 423.2262

If a plan sponsor operates in the jurisdiction of more than one of the CMS Regions, marketing materials should be submitted to the appropriate reviewer in the lead region (e.g., the region where the plan sponsor’s Account Manager is located). Multi region 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 in HPMS.

90.17 - File & Use Retrospective Monitoring Reviews

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262(b), 422.2264, 423.2262(b), 422.2264

CMS will periodically 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, of their responsibility to adhere to CMS requirements and to submit an electronic attestation at the time a material is submitted.

90.18 - Specific Guidance on the Submission of Websites for Review

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262, 423.2262

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 forty-five (45) day review through HPMS under category code 4006-Internet web pages. CMS expects reviewers to have an opportunity to review the link(s) provided as the information will be displayed in the marketplace. Therefore, the reviewer should be able to conduct the review online using the links provided in the Word document. Submitting screen shots or text in a word document is not acceptable. If the option to view online is not feasible, the organization should contact the Account Manager (prior to submission) and receive permission to submit information other than through a live link.

Once a plan sponsor's website is reviewed and approved in entirety, a plan sponsor may update specific pages of this same website by submitting only the pages to be changed using the same submission process as described above (submit a link in a Word document for a forty-five (45) day review). Any updates to pages should be submitted with their own unique material id and date stamped accordingly. Plan sponsors should submit any previously approved web pages or sites links for review if there are any changes or updates related to Medicare or plan benefit information.

Plan sponsors must include a date stamp on each Web page to indicate when it was last updated. 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. In this instance, plans do not need to include a date for pending 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).

Plan sponsors are reminded that websites are required to meet all CMS guidelines, Section 508 of the Rehabilitation Act compliance requirements, and any other guidance noted in § 100.

90.19 – Service Area/Low Income Subsidy Materials/ Functionality (SA/LIS)- Special Guidance on Multiple Submissions of Materials

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262, 423.2262

HPMS restricts multiple submissions of *materials that have a Y in the plan designation column on the marketing look up code listing in HPMS (refer to the marketing code look-up in HPMS)*. This requirement was implemented to ensure that CMS has the ability to capture the final plan version *of materials in HPMS*. Therefore, if a plan sponsor attempts to upload a *material with this classification (e.g., SB, 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 *materials with this classification*, plans *should use the SA/LIS functionality in HPMS. Plans should select the alternate format function in HPMS when submitting non-English versions of materials with this classification.*

90.21 - Materials Not Subject To Review

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 all the applicable requirements in these Medicare Marketing 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 *for* Civil Rights)
- Press releases that do not include any plan-specific information (e.g., information about benefits, premiums, co-pays, deductible, benefits, how to enroll, networks)
- 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 that do not include promotional language
- General health promotion materials that do not include 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 Part D, MA, or section 1876 cost plans (e.g., notice of check return for insufficient funds, letter stating Medicare ID number provided was incorrect, billing statements/invoices, sales, and premium payment coupon book)

- Sales representative recruitment and training documents
- 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 notifications (as provided in § 50.2 of Chapter 14 of the Medicare Prescription Drug Benefit Manual)
- Health Risk Assessments
- Mail order pharmacy election forms
- Other member surveys
- VAIS (refer to § 110)

90.22 - Submission of Multi Plan Materials

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262, 423.2262

CMS will issue guidance on a multi-plan material submission process.

100.1 - Plan Sponsor Website Requirements

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2264(a), 423.2264(a)

All plan sponsors, including section 1876 cost plans, must have a website or web page dedicated to each product they offer (with the exception of employer based plans; refer to § 130). This website/page must include the name of the plan sponsor and clearly indicate that it is a Medicare contractor (See § 50 regarding marketing material types and applicable disclaimers). All marketing materials that include a web address for the sponsor’s website should link directly to the organization’s Medicare specific pages.

CMS expects that plans will design their Medicare-related website(s) with beneficiaries as the primary audience. 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. Plan sponsors should reference § 170 to ensure compliance regarding the use of beneficiary information

requirements. In addition, any formulary information placed on websites must comply with § 60.5.4 in addition to § 100 of the guidance.

Any marketing materials that a plan sponsor places on a website must be in a minimum twelve (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 twelve (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.

Plan sponsors are allowed to utilize social networking websites (e.g., Facebook, Twitter) to promote their plan to Medicare beneficiaries. However CMS intends to monitor the use of such social networking site for this purpose in order to ensure that plan sponsors do not mislead Medicare beneficiaries. If warranted, we will issue additional guidance limiting as appropriate plan sponsors' use of social networking websites to market their Medicare products. Plan sponsors must submit advertisements that will be utilized for Facebook or Twitter for review and approval.

Any marketing materials that a plan sponsor places on its website must be in a minimum twelve (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 twelve (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 - Required Website Content

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2264, *422.111 (g) (2)* 423.2264, *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).

- *SB*
- *Enrollment instructions and forms*
- *EOC*
- *LIS Premium Summary Table*
- *Privacy Notice (privacy notices are subject to enforcement by the Office for Civil Rights)*
- *Provide a link to their transition process*

- *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*
- *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*
- *If applicable, non-English materials must be available as noted in § 30.11, 30.12, 30.13, and the Part D Transition Letter available in any language that is the primary language of more than five percent of a plan sponsor's PBP service area.*

Websites should use 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, SB, 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. For specific guidance on submission of website reviews refer to § 90.18.

CMS expects that up-to-date versions of marketing materials will be available on the website. As an example, when a plan updates their pharmacy/provider directory, the directories on the website must reflect the most up-to-date version. Similarly, if a plan issues an errata for an EOC they must ensure a corrected version of the EOC is placed on the website. CMS also expects online formularies will reflect the most recently approved formulary file.

Plan sponsors must provide certain current contract year information on a website for members and prospective enrollees. Renewing plan sponsors are also required to provide website content beginning October 1 for the next contract year. Plan sponsors must maintain current contract year content on their website until at least December 31. In addition, documents and information related to upcoming contract year content must be clearly distinguished from current contract year documents and information (for example having a splash page that allows the viewer to select information for the current plan year and/or subsequent plan year). CMS expects users will be able to quickly identify which year's information they are reviewing (e.g., 2012 Summary of Benefits and 2011 Summary of Benefits). The website content for the upcoming contracting year must be submitted to CMS as described in § 90.18 and contains all information in Appendix 2.

Plan sponsors must include a date stamp on each Web page to indicate when it was last updated. Additionally, each Web page should include the material ID at the bottom of the Web page. When a website is first approved each Web page should contain the material id used in the initial website submission. If a webpage is updated, the material ID of that page should correspond with the unique material ID for the Web page submission as indicated in 90.18.

When placing previously submitted materials on the website (i.e. SB, formulary, provider/directory), the materials should retain their unique material ID.

Plan sponsors are required to include the approved material ID on their Medicare website. For example:

- *Pharmacy directory SXXXXX_XX CMS Approved MMDDYYYY.*

In addition to the information noted in § 100.2.1, 100.2.2, 100.2.3, 100.2.4 and Appendix 2, 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.*
- *Process for contacting Social Security Office or Medicaid to inquire about LIS status or level.*

100.2.3 - Specific Guidance Regarding Grievance, Coverage Determination (including Exceptions) and Appeals Website Requirements

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 standard and expedited requests for benefits (expedited and standard) and may choose to accept oral requests for payment.*
 - 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' <http://www.cms.gov/CMSForms/CMSForms/list.asp#TopOfPage>.
- 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' Part D appeals webpage: http://www.cms.hhs.gov/PrescriptionDrugApplGriev/13_Forms.asp.

- A link to the Medicare Part D Coverage Determination Request Form (for use by provider) located on CMS' Part D appeals webpage:
http://www.cms.hhs.gov/MedPrescriptDrugApplGriev/13_Forms.asp.

100.3 - Prohibited Links

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

Federal Food Drug and Cosmetic Act

Part D plans may not provide links to foreign drug sales on their websites.

100.5 - Enrollment via the Internet

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.60, 422.2268, 423.32, 423.2268

Some plan sponsors 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 (*refer to Chapter 2 of the Medicare Managed Care Manual, and Chapter 3 of the Prescription Drug Benefit Manual for the appropriate enrollment guidance on what plan types are allowed to utilize enrollment internet mechanisms*). 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 § 40.1.2 of Chapter 3 of the Medicare 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/products as part of the online enrollment process.

In developing and submitting online enrollment screens, plan sponsors 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 Medicare 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 e-mail 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 *in response to the enrollment request – e.g.,* acknowledging receipt of the completed enrollment request, or requesting additional information *or denial of enrollment (e.g., not eligible).*

NOTE: *The only online enrollment mechanism that third party entities (on behalf of the plan sponsor) may make available to potential enrollees is via the plan sponsor’s website. The enrollment of a beneficiary utilizing an agent/broker website is not permitted. Furthermore, allowing agents/brokers – including third party plan comparisons and enrollment websites that function as brokers to assist with telephonic enrollments is prohibited. Plan sponsors must ensure that telephonic enrollment requests are effectuated entirely by the beneficiary or his/her authorized representative and that the plan representative, sales agent, or broker is not physically present at the time of the request. (Refer to section 40.1.3 of Chapter 2 of the Medicare Managed Care Manual, 40.1.3 of the Medicare Prescription Drug Benefit Manual.)*

100.5.1 - Required Materials When Online Enrollment is Utilized

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.503, 423.2260

Plan sponsors that choose to allow online enrollment via their website should refer to § 30.11 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. An exception to this is alternate formats (refer to § 90.11 for further details). Apart from compliance with section 508 of the Rehabilitation Act (refer to § 30.10), plan sponsors need only to indicate at the beginning of the online enrollment mechanism that alternate format materials are available by contacting the plan directly. 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.

110.1 - Definition of Value-Added Items and Services (VAIS)

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

Chapter 4 of the Medicare Managed Care Manual, § 90

The definition, examples, and policy requirements of VAIS are provided in Chapter 4 of the Medicare Managed Care Manual. Plan sponsors should refer to § 170 regarding use of beneficiary information for the provision of information about health-related VAIS. VAIS may be offered by MA plans, PDPs, EGWPs, and section 1876 cost plans.

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.

Since VAIS is not a benefit, therefore, it:

- May not appear in the PBP, SB *including section 3*, 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 VAIS.

120.1 - Compliance with State Appointment Laws

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2272(c), 423.2272 (c)

Plan sponsors must comply with State appointment laws. In order to sell Medicare products, an agent or broker must be appointed in accordance with the appropriate State’s appointment law and if there are any fees required as part of the appointment law, the fees must be paid. Note that CMS does not dictate who should pay any such fees.

120.2 - Plan Reporting of Terminated Agents

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2272(c), 423.2272(c), *422.2272 (e), 423.2272 (e)*

Plan sponsors must 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 must make the report available upon CMS’ request until further guidance has been issued regarding designated reporting dates to CMS.

Plan sponsors must terminate upon discovery and report incidences of submission of applications by unlicensed agents and brokers to the authority in the State where the application was submitted. Additionally, plan sponsors must notify any beneficiaries that were enrolled in their plans by unqualified agents and advise those beneficiaries of the agents and brokers status. Beneficiaries may request to make a plan change (including a special election period). Agents acting as customer service representatives are not required to hold a license and cannot engage in marketing activities.

120.3 - Agent/Broker Training and Testing

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2274(b)(c), 423.2274(b)(c)

Plan sponsors must ensure annually that *all* brokers and agents, *including those employed by MA and Part D plans*, selling Medicare products are trained and tested annually on Medicare rules and regulations and on details specific to the plan products that they sell. 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 *is* prohibited.

In order to sell Medicare products, a broker or agent *must* receive a passing score of at least eighty-five (85) percent on the test of Medicare rules and regulations. Tests may be written 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 passed the test at the appropriate level* and must have the ability to provide this information to CMS upon request.

120.4 - Agent/Broker Use of Marketing Materials

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2262, 423.2262

Plan sponsors are responsible for all marketing materials used by their subcontractors to market their plan(s). All marketing materials used by plan sponsors or their subcontractors must be submitted by the plan sponsor *that contracts with CMS (e.g., the MAO or PDP sponsor offering the plan being marketed, or, in the case of a marketing material used by multiple plan sponsors, by one plan sponsor on behalf of all affected plan sponsors)* to CMS for review and approval prior to use. Marketing materials **cannot** be submitted directly by a third party to CMS. *It is the responsibility of plan sponsors to ensure that all applicable materials created by a third party meet the requirements outlined in the MMG.*

Agents and brokers are permitted to create and distribute *materials*. *Materials that mention Medicare or plan specific benefits must be submitted to CMS for review and approval or File & Use if applicable via the plan sponsor.* Business cards indicating the products (for example HMO, PPO, or PDP) that he/she is selling for a specific plan or plan(s) *are not required to be submitted to CMS for review*. Please note that this guidance in no way precludes the application by the plan sponsors of more stringent rules or contractual obligations in order to further restrict agent or broker communication.

Additionally, agent/brokers who wish to use materials containing plan information from multiple plan sponsors can either have the piece submitted and approved by CMS for each plan sponsor mentioned prior to use.

120.5.4 - Specific Guidance for Developing and Implementing Compensation Strategy

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2274(a), 423.2274(a)

Following is specific guidance for plan sponsors as they develop or modify their agent/broker compensation strategy.

- CMS defines "year" as a plan year, meaning January 1 through December 31. For example, if a beneficiary turns 65 in and enrolls in a plan in September, then the initial year for that beneficiary ends on December 31st of that year, even though the beneficiary has only been in the plan for four (4) months. In January of the next year, the plan would begin paying renewal payments to the agent that assisted this beneficiary. When a beneficiary enrolls after January 1, the plan sponsor must pay the agent/broker at the initial compensation level during that calendar year but may pay either the full commission or a pro-rated amount based upon the number of months the beneficiary was enrolled. The plan sponsor has the discretion to provide this compensation in a single payment or multiple payments at anytime during the year. Compensation of the agent/broker for the remainder of the six (6)-year commission cycle must be at the renewal commission level. The renewal commission may also be paid at any time during each year of the cycle and may be paid in a single payment or multiple payments.
- 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 must not pay agents who are no longer appointed to sell in the State (if required), agents who have not been annually trained and tested per the plan's policies and procedures with a passing score of eighty-five (85) percent, or agents who have been terminated for cause by the plan.
- CMS does not differentiate between agents, brokers, general agents, general agencies, *TMOs*, 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 *represents a single plan sponsor and is paid a fixed amount of money that does not vary based on enrollment*, 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 prohibits plans from paying compensation in advance (e.g., paying five (5) years' residuals up front).

- Referral fees are equivalent to finder's fees and governed by CMS regulations. This means that referral fees must be included in compensation schedules and fall within CMS compensation rules. While referral fees are part of total compensation, they are a one-time fee and not subject to the six (6)-year compensation cycle.
- Bonuses (announced or unannounced prior to payment) must be included in compensation schedules 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 section 1876 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. Plan sponsors should not pay both the MA and PDP compensation amounts.
- For Medicare beneficiaries enrolling in a plan mid-year and having no prior plan history as indicated on the compensation report, plan sponsors may pay the full year initial compensation amount.
- A plan sponsor will have the opportunity prior to each contract year to determine that it will no longer use independent agents and brokers. When a plan sponsor and/or a contracted independent agent or broker elect to terminate their contract, any remaining cycle years of existing business will be governed by the terms of that contract.

120.5.5 - Compensation Calculation

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2274(a), 423.2274(a)

The aggregate compensation amount paid for selling or servicing an enrollee during each of the five individual renewal years of a six (6)-year cycle must be fair-market value (FMV) for the work performed and no more, and no less, than fifty (50) percent of the aggregate compensation amount paid for that beneficiary in the initial year of the six (6)-year. In addition, all parties should ensure that their compensation arrangements including arrangements with *TMOs* and other similar type entities comply with all fraud and abuse laws, including the Federal anti-kickback statute.

120.5.8 - Third Party Marketing Entities

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2274(a), 423.2274(a)

If the plan sponsor contracts with a third party entity such as a *TMO* or a 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 for the enrollment must be consistent with the compensation requirements (See §120.5.5). The amount paid to the third-party for other services

must be of FMV 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 two (2) years.

120.6 - Activities That Do Not Require the Use of State-Licensed Marketing Representatives

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

42 CFR 422.2274(c), 423.2274(c)

Some plan activities, typically carried out by the plan sponsor's customer service department do not require the use of State-licensed marketing representatives. These include the following:

- Providing factual information
- Fulfilling a request for materials
- Taking demographic information in order to complete an enrollment application at the initiative of the prospective enrollee.

The examples above are legitimate customer service activities that would not require using State-licensed marketing representatives.

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 prospective enrollees who have already decided to request enrollment 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.

Plan sponsors are reminded that they may not require potential enrollees to interact with a licensed agent in order to obtain plan material or to enroll in a plan if the potential enrollee is not asking for advice or counseling. Further, agents cannot act as a customer service representative and agent simultaneously. *There are occurrences when a plan sponsor, TMOs or other third-party may employ individuals with the intent to act as both an agent and a customer service representative. In these instances, there should be a clear distinction within the organization as to the type of representative that will be answering calls, their precise roles and level of knowledge and training. The level of knowledge, training and licensure dictates a representative's appropriate responsibilities. For example, a licensed agent has a higher level of training and may perform the duties within the scope of a customer service representative as described above. However, an unlicensed call center representative is not qualified to perform duties beyond their degree of knowledge, training and licensure. When an unlicensed customer service representative encounters questions from a beneficiary that are beyond the scope of their abilities, they must advise the caller to call a specified number and speak to a licensed agent for further guidance regarding plan choices.*

140.2 - MSA Explanatory Marketing Materials Requirements

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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.
 - Live outside of the United States more than one hundred eighty three (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 statement:

*“Enrollment is generally for the full calendar year. You can disenroll from <Plan Name> from **October** 15 and December **7** of each year. Your disenrollment will be effective January 1 of the next year. 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 the following statement 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 filing 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 fifty (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.”*
- *“Tax publications are available on the IRS website at <http://www.irs.gov> or from 1-800-TAX-FORM (1-800-829-3676).*

150 - Use Of Medicare Mark For Part D Plans

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

Section 1140 of the Social Security Act

All MA-PD plans, PDPs, section 1876 cost that provide Part D benefits will *sign* a licensing agreement to use the official Medicare Mark via *the HPMS contracting module. All applicant and renewing Part D sponsors will sign the Medicare Mark licensing agreements via the HPMS electronic signature process. The license agreement is effective for a single contract year and Part D sponsors must renew annually to continue using the Medicare Mark logo.*

150.1 - Authorized Users for Medicare Mark

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 in order to

use the Medicare Prescription Drug Benefit Program Mark prior to execution of the Part D contract. PDP and MA-PD entities may use the mark on submission of marketing materials consistent with this chapter.

150.3 - Approval to Use the Medicare Prescription Drug Benefit Program Mark

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

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 approval of a Part D plan via HPMS contract approval process, CMS will distribute the Medicare Prescription Drug Benefit Program Mark licensing agreement to those entities. After CMS has received the signed licensing agreement back from the organizations, *and the contract document for the upcoming year has been counter-signed*, 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 (materials that are not included in this chapter) bearing the Medicare Prescription Drug Benefit Program Mark must be submitted to CMS at least thirty (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.

160 - Use of Federal Funds

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

(Division F, Title V, § 503(b), Departments of Labor, HHS, and Education Appropriations Act, 2009, as enacted by § 5, Omnibus Appropriations Act, 2009, Pub. L. 111-8, 123 Stat. 524, 802 (March 11, 2009))

CMS prohibits the use of Federal funds for non-plan related activities that are designed to influence State or Federal legislation or appropriations, by MAOs, Part D sponsors, section 1876 cost plans, PACE plans, and MA demonstration plans. Specifically, the Department of Health and Human Services' *Annual Appropriations Acts* very specifically *states* that no appropriated funds may be used to pay the "salary or expenses of any grant or contract recipient, or agent

acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.”

170.4 - Sending Non-plan and Non-health Information Once Prior Authorization is Received

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

Non-plan and non-health related content cannot be provided to members until after prior authorization is received. Once the authorization is received:

- Non-health related content cannot be included with plan-related materials. This includes mailings and websites, as well as outbound telephone calls related to current plan information. Note that if the plan sponsor uses a website to provide non-health related content, the link from the plan’s Medicare product website must inform the beneficiary that he or she is leaving the Medicare product website and going to the non-Medicare product website as specified in § 100.1.
- Health-related content can be included with plan-related materials.
- As with all other materials that plans send to Medicare beneficiaries, plan sponsors are responsible for ensuring that any non-plan related content provided as a result of beneficiary authorization is accurate and not confusing or misleading, and does not inappropriately imply Medicare’s approval, or suggest that the content includes official information from the Medicare program. In addition, these materials should include the disclaimer, “Medicare has neither reviewed, nor endorses, this information.” (Refer to § ***15.1.13***) This also includes any mailing envelopes in which the non-plan related information is sent. Plan sponsors must also include a plan mailing statement on such materials as specified in § 50.2.

If the plan sponsor wishes to include the request for authorization in plan mailings, as opposed to a separate mailing at its own expense, the claimed administrative costs must reflect an appropriate reduction to reflect the share of the document preparation and mailings cost that is attributable to the sponsor’s efforts to seek authorization to send non-plan related materials. (refer to § 40.14.1 and 40.14.2).

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. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

[Applies to MA-PD, PDP and MA plans]

CMS expects that the language for sections I and II will be identical to the SB report in HPMS. Any deviation from this language, outside of an approved hard copy change or global hard copy change, will result in CMS disapproval of the material. Deviations include things like the insertion of footnotes, plan specific clarifications, or format alterations except as indicated in the SB instructions. Plans should be generating their SB via the path in HPMS.

General requirements and guidance for SB are provided below:

1. Plan sponsors 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 (e.g., all three sections OR sections one and two if section three is not being utilized).
4. The entire SB must be submitted for review as one document. If plans opt to utilize the premium table and/or Section III and/or Section IV *it* will result in a forty-five (45) day review.
5. Front and back cover pages are acceptable.
6. Font size of twelve (12) point or larger must be used for the SB.
Plan sponsors 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 I and II of the SB will not be generated from the PBP in twelve (12) point font, the MA organization should change the font to ensure that the font size is twelve (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. Plan sponsors 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 II). *Plan sponsors must only include similar plan types when describing several plans (i.e., HMO to HMO but not HMO to PFFS or HMO to PPO).* However since the PBP will only print Sections I and II of the SB report for one plan, the plan sponsor will have to create a side-by-side comparison matrix for two (or more) plans by manually combining the information into a chart format. Plan sponsor using this format must include the following statement in Section I: “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 I will conflict between MA and MA-PD plans, plan sponsors will need to make a hard copy change for Section I 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. *Side-by-side comparisons should be submitted to the regional office for review and approval.*

10. Plan sponsors 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 II). Plan sponsors using this format must include the following statement in Section I: “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. Plan sponsors may include additional information about covered benefits within a separate flyer or other material and may provide this with the SB.
12. The SB header containing such information as the company name, customer service telephone number, only displays on the first page of the SB Section II. It is acceptable for plan sponsors 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.
13. If an organization chooses to submit an SB for CMS review, without Section III and no hard copy changes, it will be treated as a model without modification and will be reviewed within the ten (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 III 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 III, 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 I – Beneficiary Information

[Applies to MA-PD, PDP and MA only]

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

NOTE: The last sentence in Section I *will automatically include the following*, “*This document may be made available in other formats such as Braille, large print or other alternate formats.*” Plan sponsors 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 I, 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 I 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 III and list the zip codes here.
4. Refer to #s 9 and 10 in the SB General Instruction section above for information on additional sentence requirements for Section I of the SB.

Instructions for Section II – 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 benefit 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 III – Plan-Specific Features

Section III is used by plan sponsors to describe special features of a program or to provide additional information about benefits described within Sections I and II. Section III 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 six single-sided pages or three double-sided pages. However, there is one exception to this limit: Plan sponsors translating the SB to another language may add pages as necessary to ensure the translation conveys the same information as the English language version.

Plan sponsors may provide additional information in Section III about covered benefits described within the benefit comparison matrix. If the organization chooses to further describe its covered benefits in Section III, 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 III must be verified with the information entered into the PBP report in HPMS.

Section IV of Template for DE Special Needs Plans:

Effective 2010 and beyond, a comprehensive written statement is a MIPPA requirement for all DE SNPs. The purpose of this requirement is to help prospective enrollees to determine whether they can receive any value from enrolling in a SNP. This requirement applies to all DE SNPs regardless of whether they have a contract with the state

Comprehensive written statement must cover benefits and cost sharing information under SNP and State Medicaid plan. A template with the required format is available in HPMS under the bid submission module. In order for plans to describe their benefits, the Section IV SB template can be downloaded using the following navigation path: Plan Bids>Bid Submission>CY XXXX>Documentation>SB Template for DE SNPS.

Adding only Section IV to the SB will trigger a 45-day review process. If a plan does not have a Section III, the Medicaid language does not have to be labeled as Section IV, but it must be distinct from Sections I-III of the SB. Plans should not substitute SB Section III with Section IV. In addition, the format for Section IV is standardized and should be not altered in any way, unless otherwise directed by CMS.

Plan may use the following disclaimers in Section IV of the SB:

1. Applies to all dual SNPs that cover all duals - “The services listed below are available only to those SNP members eligible under Medicaid for medical services.”
2. Applies to fully integrated SNPs that have integrated benefits in SB Section II - “Many of the services that are covered by Medicaid are also covered by Medicare through your Medicare Advantage SNP. These services are not listed below. Only the services that may continue when Medicare coverage ends, or which are not covered by Medicare are shown.”

Fully Integrated DE SNPs: For fully integrated DE SNPs that meet requirements I- IV, CMS will allow plans to modify Section II of the SB to reflect integrated benefits applicable to each benefit category.

1. Provides dually eligible beneficiaries access to Medicare and Medicaid benefits under a single managed care organization (MCO);
2. Has a contract with a state Medicaid agency that includes coverage of specified primary, acute and long-term care benefits and services, consistent with State policy, under risk-based financing;
3. Coordinates the delivery of covered Medicare and Medicaid health and long-term care services, using aligned care management and specialty care network methods for high-risk beneficiaries; and
4. Employs policies and procedures approved by CMS and the state to coordinate or integrate member materials, including enrollment, communications, grievance and appeals, and/or quality assurance.

SB Place Holder Sentences: For MA-PD and MA only

Plans have the option to use the prior year's Medicare premium and deductible amounts instead of waiting for CMS to release the new year's amounts. MAOs that apply the Medicare-defined cost sharing for Inpatient Hospital Acute, Inpatient Hospital Psychiatric and Skilled Nursing Facility may also use the prior year's Medicare cost sharing amounts.

Based on this option, for example, the SB will print both the prior year's Medicare cost sharing amounts and a place holder sentence for the new year's Medicare cost sharing amounts. Plan sponsors that need to go to production prior to CMS' release of the Medicare cost sharing may use the prior year's Medicare cost sharing amounts and sentences and delete the new year's placeholder sentences. Plan sponsors that can wait until CMS releases the new year's Medicare cost sharing should use the new year's placeholder sentences and manually update the SB with the new year's Medicare cost sharing when the amounts are released. In addition, these plan sponsors should delete the prior year's Medicare cost sharing amounts and sentences. Medicare Options Compare will automatically display new Medicare cost sharing amounts.

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 II: 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 II and before Section III. 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.*"
- *Regional Copay/Premium Table: When Organizations or Sponsors offer plans with identical benefits in multiple regions, they may create a regional copay or premium table to accompany the SB that lists the copays/premiums for all regions covered. Include with the table, should be an instruction to members explaining how to find the co-pay and premium information that applies to them. The regional copay/premium table and SB is required to be submitted and reviewed by CMS with an attestation that the information populated in the table is identical to what is approved in the bid.*

SBs with only Sections I, II and the Premium Table are subject to a 45-day review.

Requests to Change Hard Copy SB [Applies to all organizations/plan types]

CMS will allow an organization to make changes to hard copy SBs on a very limited basis. All Plan sponsors 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
- 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]

Hard copy change requests must be submitted via the SB hard copy change module in HPMS

When requesting a hard copy change, *plan sponsors* should provide:

- The contract number and PBP #(s) and the regional office reviewer responsible for SB review;
- The existing standardized SB language;
- An explanation of why the existing standardized language is inaccurate; and
- A modified sentence.

SB for Section 1876 Cost Plans

[Applies to Section 1876 cost plans – see information below]

Section 1876 cost plans are not required to use the standardized Summary of Benefits. If section 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. Section 1876 cost plans that create a standardized SB, they should follow all instructions below. All section 1876 cost plans should follow all instructions previously outlined for the SB. In addition, the following instructions are specific to section 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, section 1876 cost plans should choose all of the applicable sentences in each category to describe their benefits.

Instructions for Section I- Beneficiary Information Section – For section 1876 cost plans

For section 1876 cost plans that are “closed” to new enrollment, the pre-enrollment language in Section I will not apply *to existing members*. Therefore, these section 1876 cost plans should include the following disclaimer in their ANOC: *“Existing Cost Plan members should disregard the Introduction of Section I of the Summary of Benefits (SB).”*

NOTE: Any additional information regarding the contractor’s “closed status” should also be included in the cover letter.

Instructions for Section II - Benefit Comparison Matrix – For section 1876 cost plans

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 - Plan Sponsor Website Chart

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

The following chart applies only to URL guidelines and plan sponsors 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 plan sponsors must maintain a Web page, or, if they choose, a website dedicated to the Medicare Advantage or Prescription Drug program.</p> <p>All marketing materials can include a Web address that connects to either a corporate website or to the plan's Web page.</p>		Beneficiaries should be able to find a plan's program information with a minimum of difficulty.
	Website Links	<p>All links on a 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	All plan sponsors 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 plan sponsors 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 plan.

	Subject	Must Use	Must Not Use	Reason
	Font Size	All plan sponsors must use a minimum 12-point Times New Roman or equivalent font for all Internet content.		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. Therefore, the 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.
	Service Area	<p>For Part D: Regions served by the plan sponsor must be listed. If the Part D plan is a national plan, then it must be identified as such.</p> <p>For Part C: The plan must list the state(s), counties and zip codes (only if a partial service is allowed). If the Part C plan is a national plan then it must identify the states.</p>		
	Benefits	<p>For all plan sponsors:</p> <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	

Subject	Must Use	Must Not Use	Reason
	<p data-bbox="516 247 711 275">For Part D plans :</p> <ul data-bbox="516 306 906 747" style="list-style-type: none"> <li data-bbox="516 306 906 520">• 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. <li data-bbox="516 527 906 579">• Number of pharmacies in network <li data-bbox="516 585 906 747">• 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 data-bbox="516 785 906 947">If plan sponsors use a search engine on their websites in lieu of posting the Pharmacy Directory, the search engine must be in compliance with section 100 of the Medicare Marketing Guidelines.</p>		
	<p data-bbox="315 1073 448 1131">Current Formulary</p> <p data-bbox="516 1031 906 1110">All Part D plans and PDPs: Must include a current formulary, updated at least monthly.</p>		
	<p data-bbox="321 1356 441 1415">Provider Directory</p> <p data-bbox="516 1262 906 1394">All MA and section 1876 cost plans must include an electronic provider directory applicable for all products defined by service areas or general geographic area.</p> <p data-bbox="516 1436 906 1516">Plans must provide applicable notices with regards to changes that occur in the provider network.</p>		

	Subject	Must Use	Must Not Use	Reason
	<p align="center">Out-of-Network Coverage</p>	<p>For Part D and PDPs: All Part D 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.</p> <p>For Part C plans: All Part C plans must include provisions with regards to:</p> <ul style="list-style-type: none"> • Lock-in • Premiums • Cost-sharing (e.g., co-payments, co-insurance and deductibles) • Rules for obtaining out of network services • Referral rules 		
	<p align="center">Coverage Determinations, Organization Determinations, Grievance, Appeals Processes and Procedures</p>	<p>All Part D <i>plans must include a description of the grievance, appeals and coverage determination (including exceptions)</i> processes and the procedures members must follow to file a grievance, appeal or request a coverage determination. Additionally, Part D plans must include information on a Web page (located as close to the plan's formulary page as possible) developed specifically for exceptions and appeals.</p> <p>All MA plans must include a description of the grievance, <i>organization determination and appeals processes and the procedures members must follow to file a grievance or to request an organization determination or appeal.</i></p>		

	Subject	Must Use	Must Not Use	Reason
	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, quality assurance activities, and programs provided by Part C plans..		
	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>All plans must provide access to the following links:</p> <ul style="list-style-type: none"> • Summary of Benefits • Enrollment Instructions and Forms • Evidence of Coverage • LIS Premium Summary Chart • Privacy Notice • Plan Transition Process • Information related to plan's exception and appeals process • Section of CMS' website regarding Best Available Evidence 		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 data-bbox="298 646 461 764">If applicable: Notice of Formulary Change</p> <p data-bbox="516 285 894 422">For all Part D plans and PDPs 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 data-bbox="516 464 808 516">The notice must contain the following:</p> <ul data-bbox="521 558 894 1157" style="list-style-type: none"> <li data-bbox="521 558 824 611">• The name of the affected covered Part D drug; <li data-bbox="521 611 886 747">• Information on whether the covered Part D drug is being removed from the formulary, or changing its preferred or tiered cost-sharing status; <li data-bbox="521 747 886 884">• The reason why the covered Part D drug is being removed from the formulary, or changing its preferred or cost-sharing status; <li data-bbox="521 884 894 1020">• Alternative drugs in the same therapeutic category, class or cost-sharing tier, and the expected cost-sharing for those drugs; and <li data-bbox="521 1020 870 1157">• The means by which enrollees may obtain an updated coverage determination or an exception to a coverage determination. 		

Appendix 3 - Model File & Use Certification Form

(Rev. 96, Issued: 5-17-11, Effective: 5-17-11, Implementation: 5-17-11)

[Applicable to MA, MA-PD, MA only, Section 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 Medicare 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 §422.2260 – §422.2276 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.