

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

The Medicare Marketing Guidelines (MMG) implement the Centers for Medicare & Medicaid Services' (CMS) marketing requirements and related provisions of the Medicare Advantage (MA), Medicare Prescription Drug Plan (PDP), and 1876 cost contract rules, (i.e., Title 42 of the Code of Federal Regulations, Parts 422, 423, and 417). These requirements do not apply to Program of All-Inclusive Care for the Elderly (PACE) plans or 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 Social Security Act (the Act) and CMS regulations, extends beyond the public's general concept of advertising materials. Pursuant to 42 CFR §417.428, §422.2260, and §423.2260, marketing materials include any materials developed and/or distributed by those entities covered by the MMG which are targeted to Medicare beneficiaries. While not an exhaustive list, the following materials 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 circulated by physicians, other providers, or third-party entities.
- 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, (e.g., 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, or may receive compensation directly or indirectly from a plan sponsor for marketing activities.

In addition, 42 CFR §417.428, §422.2268, and §423.2268 define the standards for marketing. Thus, CMS' authority for marketing oversight, and the MMG, encompasses not only marketing materials but also marketing/sales activities. As plan sponsors implement their programs, they should consider the following guiding principles:

- Plan sponsors are responsible for ensuring compliance with CMS' current marketing regulations and guidance, including monitoring and overseeing the activities of their subcontractors, downstream entities, and/or delegated entities.
- Plan sponsors are responsible for full disclosure when providing information about plan benefits, policies, and procedures.
- Plan sponsors are responsible for documenting compliance with all applicable MMG requirements.

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. Any new rulemaking or interpretative guidance, (e.g., annual Call Letter or HPMS guidance memoranda), may supersede the marketing guidance provided in this document. Specific questions regarding a marketing material or marketing practice should be directed to the plan sponsor's Account Manager or designated Marketing Reviewer.

Note: Marketing for an upcoming plan year may not occur prior to October 1.

20 – Materials Not Subject To Review

42 CFR 422.2260, 422.2262, 423.2260, 423.2262

The following items are materials that are not subject to review by CMS and should not be uploaded into HPMS. However, plan sponsors are still responsible for tracking and maintaining such materials so as to make them available upon CMS request.

- Privacy notices (which are subject to enforcement by the Office for Civil Rights)

- OMB Forms
- 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 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 coversheets 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" (Refer to 70.8, Educational Events)
- 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/marketing representative recruitment and training documents
- Medication Therapy Management (MTM) program material
- Ad hoc Enrollee Communications Materials (see definition in Appendix 1)
- Materials used at educational events for the education of beneficiaries and other interested parties.
- Coordination of Benefits notifications (as provided in Chapter 14 of the Medicare Prescription Drug Benefit Manual)
- Health Risk Assessments
- Mail order pharmacy election forms
- Member surveys

- VAIS materials (refer to Chapter 4 of the Medicare Managed Care Manual, § 60)
- Communicating preventive services to members
- Mid-year Change Enrollee Notifications (Refer to 60.8)

30 - Plan Sponsor Responsibilities

30.1 - Limitations on Distribution of Marketing Materials

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.

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

Joint enterprises must market their plans under a single name throughout a region. Joint enterprise marketing materials may only be distributed where one or more of the contracted plan sponsors creating the single entity is licensed by that State as a risk-bearing entity or qualifies for a waiver under 42 CFR 423.410 or 42 CFR 422.372. All marketing materials must be submitted under the joint enterprise's contract number and follow CMS requirements.

30.2 - Co-branding

42 CFR 422.2268, 423.2268

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.

The plan sponsor must inform its CMS Account Manager in writing of any co-branding relationships, including any changes in or newly formed co-branding relationships, and input this information, prior to marketing its new relationship, in the Health Plan Management System (HPMS).

30.2.1 - Co-branding with Providers or Downstream Entities

42 CFR 422.2268(n), 423.2268(n)

Plan sponsors are prohibited from displaying the names and/or logos of co-branded 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, (e.g., physicians, hospitals, and pharmacies).

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

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

Neither the plan sponsor nor its co-branding partners, whether through marketing materials or other communications, may imply that the co-branding partner is endorsed by CMS, or that its products or services are Medicare-approved. Co-branded marketing materials must be submitted to CMS by the plan sponsor.

NOTE: Consistent with the National Council for Prescription Drug Program's (NCPDP's) "Pharmacy and/or Combination ID Card" standard, the Pharmacy Benefit Manager (PBM) name may be included on a member ID card.

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

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.

30.3 – Disclosure of National Committee for Quality Assurance’s (NCQA) Approval Information

Plan sponsors may not discuss numeric Special Needs Plan (SNP) approval scores in marketing materials or press releases. Plans may only disclose the NCQA disclaimer language provided in Section 50.5.

30.4 - Use of Medigap Data to Market MA/PDP/Cost Plans

42 CFR 422.2268, 423.2268

A plan sponsor that is also a Medigap issuer may market its MA, PDP, or cost plan products to its Medigap customers.

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

42 CFR 422.504, 423.505, 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 (or its designee) to CMS for review and approval (or acceptance).

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

Materials created by agents or brokers that mention plan specific benefits must be submitted by the plan sponsor to CMS. Materials that only indicate the products, (e.g., HMO, PPO, or PDP), an agent sells are not required to be submitted to CMS. 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 and activities.

30.6 - Anti-Discrimination

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. Plan sponsors may not target beneficiaries from higher income areas or state or otherwise imply that plans are available only to seniors rather than to all Medicare beneficiaries. Only SNPs 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. Basic services and information must be made available to individuals with disabilities, upon request.

30.7 - Requirements Pertaining to Non-English Speaking Populations

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 or limited English proficient (LEP) 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.

Plan sponsors must make the marketing materials noted in §§ 30.8, 30.9, 30.12 and the Part D Transition Letter available in any language that is the primary language of at least five (5) percent of a plan sponsor's plan benefit package service area.

NOTE: The member ID card is excluded from this requirement.

Final populated versions of all materials must be uploaded into HPMS.

30.7.1 – Multi-Language Insert

The Multi-Language Insert is a document that contains information translated into multiple languages: (e.g., Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese).

"We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1-xxx-xxx-xxxx]. Someone who speaks [language] can help you. This is a free service."

Regardless of the 5 percent service area threshold (See 30.7), all plans must include the CMS created Multi-Language Insert with the Summary of Benefits and the ANOC/EOC. Plan sponsors have the option to incorporate

the multi-Language Insert as part of these materials or to provide as a separate document.

Please see Appendix 4. The Multi-Language Insert cannot be modified except to include additional languages. If a plan sponsor chooses to include additional languages on the insert, they must do so by translating the statement referenced above.

Note: D-SNPs who work with States that have more stringent language requirements must work with CMS to determine whether those requirements can be incorporated into the CMS Multi-Language Insert or may be met another way.

30.8 - Required Materials with an Enrollment Form

42 CFR 422.111, 423.128

When a beneficiary is provided with enrollment instructions/form, s/he must also receive Plan Ratings information (as specified in 30.12), the Summary of Benefits, and the Multi-Language Insert (see § 30.7.1).

NOTE: When a plan sponsor enrolls a beneficiary online, it must make these materials available electronically, (e.g., via website links) to the potential member prior to the completion and submission of the enrollment request.

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

42 CFR 422.111, 423.128, 422.2264, 423.2264

- Annual Notice Of Change /Evidence Of Coverage (ANOC/EOC) or EOC as applicable
- 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, this is required at time of enrollment, see § 60.4 for additional information)
- Provider directory (For all plan types except PDPs, this is required at time of enrollment, see § 60.4 for additional information)

- Membership Identification Card (required only at time of enrollment and as needed or required by plan sponsor post enrollment)

These documents 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 month prior to the effective date, whichever occurs first. Plan sponsors should refer to the date of the Transaction Reply Report (TRR) that has the notification to identify the start of the ten (10) calendar day timeframe.

30.9.1 – Mailing Materials to Addresses with Multiple Members

42 CFR 422.111, 423.128, 422.2264, 423.2264

Every member must receive the materials noted in 30.9 at the time of enrollment. Thereafter, plan sponsors have the option of mailing these materials to either every member or every address where up to four members reside. Individuals in apartment buildings are only considered to be at the “same address” if the apartment number is the same. Individuals living in community residences, (e.g., group homes or nursing facilities), must each receive their own materials, regardless of whether they have the same address.

If a plan sponsor chooses to mail the materials noted in 30.9 to one address where up to four members reside, they must either include the names of all enrollees on the envelope or list one name on the envelope and include all others on a cover letter accompanying the mailing.

Note: Plan sponsors may not mail one membership identification card to an address where multiple members reside; all enrollees must receive individual membership identification cards.

30.10 - Hold Time Messages

42 CFR 422.2268(f) and 423.2268(f)

Hold time messages may not include non-health related items, (e.g., life insurance, disability, etc.). Hold time messages that promote the plan or include benefit information must be submitted in HPMS.

30.11 – Member Referral Programs

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 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.
- Gifts must be of nominal value (refer to §70.1- Nominal Gifts).

30.12 - Plan Ratings Information from CMS

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

Plan sponsors must provide overall Plan Ratings information to beneficiaries through the standardized Plan Ratings information document. The Plan Ratings information document must be distributed with any enrollment form and/or Summary of Benefits. This document must also be available on plan websites.

To create this document, plans must download performance rating information from HPMS using the following navigation path: HPMS Homepage >Quality and Performance > Part C Performance Metrics or Part D Performance Metrics and Reports > Part C or D Plan Ratings Template.

Plan sponsors have the option to add their plan logo to the document. No additional alterations may occur unless otherwise directed by CMS.

Plan performance ratings are generally issued in October of each year. Plans will be required to use updated Plan Ratings information within 15 days of the release of the updated information.

New plans that do not have any Plan Ratings information are not required to provide Plan Ratings information until the new contract year.

30.12.1 – Referencing Plan Ratings in Marketing Materials

- Plan sponsors may only reference the contract’s individual measures in conjunction with its overall performance rating in marketing materials.

Plan sponsors may not use their star rating in a lower category or measure to imply a higher overall plan rating in their marketing materials than is actually the case. For example, a plan which received a 5-star rating in customer service promotes itself as a “5-star plan,” when its overall plan rating is actually only 2-stars. Sponsors must use their star ratings in marketing materials in a manner that does not mislead beneficiaries into enrolling in plans based on inaccurate information.

- Plan sponsors must include the disclaimer noted in Section 50.14 on materials that refer to star ratings.
- Plan sponsors may direct beneficiaries to www.Medicare.gov for more information on Plan Ratings.
- Plan sponsors’ marketing may not reference or include poor performance status information as a means to circumvent enrollment and disenrollment election period rules. The option for beneficiaries enrolled in poor performing plans to request a special enrollment period does not create an opportunity for plan sponsors to conduct marketing activities related to this special enrollment period.
- Plan sponsors with an overall 5-star rating have the option to include CMS’ gold star icon on marketing materials. The icon must be included in a way that is not misleading and makes it clear to the audience that the 5-star rating is for a specific contract(s), as applicable. Parent organizations with only one 5-star contract should not create materials in a way that implies that all of its contracts achieved this rating. CMS will provide the gold star icon to plan sponsors.

NOTE: Plan sponsors are responsible for translating Plan Ratings information as specified in § 30.7. Translation of Plan Ratings information will not be considered an alteration of the document.

30.12.2 –Plans with an Overall Five-Star Rating

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

Plan sponsors with an overall 5-star rating may market their ability to enroll beneficiaries through the 5-star special enrollment period (SEP).

If a plan sponsor with an overall 5-star rating is assessed a rating of less than 5-stars for the upcoming year, the sponsor must discontinue marketing for the purposes of accepting enrollments under the 5-Star SEP by November 30 of the current year.

40 - General Marketing Requirements

40.1 - Marketing Material Identification

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 (except as indicated below).

The material ID is made up of two parts: (1) plan sponsors' contract or MCE number, (i.e., H for MA or section 1876 cost plans, R for regional PPO plans (RPPOs), S for PDPs, or Y for Multi-Contract Entity (MCE) identifier) followed by an underscore; and (2) any series of alpha numeric characters chosen at the discretion of the plan sponsor. Use of the material ID on marketing materials must be immediately followed by the status of either approved, pending (for websites only), or accepted (e.g., Y1234_drugx38 CMS Approved).

The following marketing materials do not require a marketing material ID number on them:

- The member ID card (although PDP or MA-PD member ID cards must include the CMS contract number and PBP number on them).
- Envelopes, radio ads, outdoor advertisements, banner or banner-like ads, and social media comments and posts.

NOTE: Refer to § 90.2.4 for additional guidance on the multi-plan material ID requirements.

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

42 CFR 422.2264(e), 423.2264(e)

Non-English or alternate format materials must be given a unique material ID as outlined above. When submitting these materials, plan sponsors must designate that they are non-English or alternate format versions in HPMS.

40.2 - Font Size Rule

42 CFR 422.2264, 423.2264

All text included on materials, including footnotes, must be printed with a font size equivalent to or larger than Times New Roman twelve (12)-point. The equivalency standard applies to both the height and width of the font.

Exceptions:

- Television Ads
- ID cards
- Internal tracking numbers
- Logos/logos with taglines
- If a plan sponsor publishes a notice to close enrollment in the Public Notices section of a newspaper, the plan sponsor does not need to use twelve (12)-point font and can instead use the font normally used by the newspaper for its Public Notices section.

Note: Because neither CMS nor the plan sponsor has any control over the actual screen size shown on individuals' computer screens that can be adjusted by the user, for Internet marketing materials, the twelve (12)-point font requirement refers to how the plan sponsor codes the font for the Web page, not how it actually appears on the user's screen.

40.3 - Reference to Studies or Statistical Data

42 CFR 422.2264, 423.2264

Plan sponsors may only compare their plan to another plan by referencing a study or statistical data as described below.

- Plan sponsors must provide the study sample size, number of plans surveyed, publication date, and page number in the HPMS marketing material transmittal comments field when uploading the document that includes the reference.

Plan sponsors must provide the following information, either in the text or as a footnote, on marketing pieces that mention a study:

- The source and date of the study.
- Information about the plan sponsor's relationship with the entity that conducted the study.

- The study sample size and number of plans surveyed (unless the study that is referenced is a CMS study).
- Reference information, (e.g., publication, date, page number), for CMS studies.

40.4 - Prohibited Terminology/Statements

42 CFR 422.2264, 423.2264

CMS prohibits the distribution of marketing materials that are materially inaccurate, misleading, or otherwise make material misrepresentations.

Plan sponsors may not:

- Claim that they are recommended or endorsed by CMS, Medicare, or the Department of Health & Human Services (DHHS).
- Use absolute superlatives, (e.g., “the best,” “highest ranked,” “rated number 1”), unless they are substantiated with supporting data provided to CMS as a part of the marketing review process. If the material is submitted via the file & use program, the supporting data must be included, along with the materials that use an absolute superlative.
- Compare their organization/plan(s) to another organization/plan(s) by name unless they have written concurrence from all plan sponsors being compared, (e.g., studies or statistical data as described in § 40.3). This documentation must be included when the material is submitted in HPMS.

Plan sponsors may:

- State that the plan sponsor is approved for participation in Medicare programs and/or that it is contracted to administer Medicare benefits.
- Use the term “Medicare-approved” to describe their benefits and services within their marketing materials.
- Use qualified superlatives, (e.g., “one of the best,” “among the highest rank”).

40.5 - Logos/Tag Lines

42 CFR 422.2268(o), 423.2268(o)

Plan sponsors may use unsubstantiated statements in their logos and in their product tag lines, (e.g., "Your health is our major concern," "Quality care is our pledge to you," "XYZ plan means quality care"). However, plan sponsors cannot use superlatives in logos/product tag lines, (e.g., "XYZ plan means the first in quality care" or "XYZ Plus means the best in managed care").

40.6 - Identification of All Plans in Materials

42 CFR 422.2264, 423.2264

Plan sponsors are not required to market all plan offerings in their service area. Plan sponsors may identify or mention more than one plan in a single marketing piece, so long as there is a distinction made between plan type and benefits offered (if benefits are mentioned in the piece).

40.7 - Product Endorsements/Testimonials

42 CFR 422.2264, 423.2264, 422.2268, 423.2268

Product endorsements and testimonials must adhere to the following:

- The speaker must identify the plan sponsor's product by name.
- A Medicare beneficiary may offer endorsement of a plan or promote a specific product, provided the individual is a current member of the plan being endorsed or promoted. If the individual is paid to endorse or promote the plan or product, this must be clearly stated, (e.g., "paid endorsement").
- If an individual, such as an actor, is paid to portray a real or fictitious situation, the ad must clearly state it is a "Paid Actor Portrayal."
- The endorsement or testimonial cannot use any quotes by physicians, health care providers, and/or by Medicare beneficiaries not enrolled in the plan.
- The endorsement or testimonial cannot use negative testimonials about other plans.

40.8 - Hours of Operation Requirements for Marketing Materials

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

Plan sponsor hours of operation must be listed on every material where a customer service number is provided for current and prospective enrollees to call.

Note: The hours of operation need to only be listed once in conjunction with the customer service number, they do not need to be listed every time a customer service number is provided.

- 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, (i.e., 24 hours a day/7 days a week).
- Customer service call center hours must be the same for all individuals regardless of whether they speak another language or use assistive devices for communication.
- ID cards are excluded from this requirement.

Refer to § 80.1 for additional guidance.

40.8.1 – Agent/Broker Phone Number

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 TTY numbers must also be included. Business cards are excluded from this requirement.

40.9 - Use of TTY Numbers

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:

- Outdoor advertising (ODA) or banner/banner-like ads.

- The Multi-language Insert (Appendix 4).
- Radio ads.
- In television ads, the TTY number may be a different font size/style than other phone numbers to limit possible confusion. Plan sponsors may 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).

40.10 - Additional Materials Enclosed with Required Post-Enrollment Materials

42 CFR 422.111, 423.128

Unless otherwise directed, plan sponsors are permitted to enclose other materials related to benefits or plan operations in their post-enrollment packages (e.g., health education newsletters, Medication Therapy Management Program (MTMP) materials, mail service forms for Part D drugs, etc.). These materials:

- Must be distinctly separate (e.g., folded or different color pages), from the required document within the mailing envelope.
- May not include advertising materials, (e.g., materials advertising additional products such as Medigap by the plan sponsor).
- Must comply with all relevant laws and regulations.

Note: Additional materials may not be included in the ANOC/EOC mailing unless otherwise specified.

40.11 - Marketing of Multiple Lines of Business

42 CFR 422.2268, 423.2268

Plan sponsors may market other lines of business (both health-related and non health-related) when marketing covered plans, provided that such materials are in compliance with applicable State law governing the other lines of business. When doing so plan sponsors are encouraged to adhere to the requirements set forth in this Section, as well as Section 160.

40.11.1 - Multiple Lines of Business - General Information

42 CFR 422.2268, 423.2268

Plan sponsor marketing materials sent to current members describing other health-related lines of business must contain instructions that describe how individuals may opt out of receiving such communications. Plan sponsors must ensure individuals (including non-members) who ask to opt out of receiving future marketing communications are not sent such communications. In marketing multiple lines of business, plan sponsors must comply with the Health Insurance Portability and Accountability Act (HIPAA) rules outlined in Appendix 2 and § 160 regarding use of beneficiary information.

Plan sponsors that advertise multiple lines of business within the same marketing document must keep the organization's lines of business clearly and understandably distinct from the other products.

Plan sponsors must not include enrollment applications for competing lines of business, (e.g., MA-PD or MA plans and Medigap products), or for other non-Medicare lines of business in mailings that combine Medicare plan information with other product information.

40.11.2 - Multiple Lines of Business - Exceptions

42 CFR 422.2268, 423.2268

Plan sponsors that send out non-renewal notices may only provide information regarding other Medicare products (such as other MA-PDs available in the service area) to those members receiving the non-renewal notice. These additional materials must be a separate enclosure within the same envelope. Enrollment applications are prohibited from being provided with non-renewal information.

40.11.3 - Non-Benefit/Non-Health Service-Providing Third Party Marketing Materials

42 CFR 422.2268, 423.2268

Non-benefit/non-health 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/non-health service-providing third party entity.

Example A: Company XYZ promotes health and wellness and develops materials targeted to the Medicare population.

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/non-health servicing third party individual to distribute the materials to their plan membership and/or to prospective enrollee.

If a non-benefit/non-health 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. See § 50.13.

40.12 - Providing Materials in Different Media Types

42 CFR 422.64, 422.111, 423.48, and 423.128; Social Security Act

[§1852(c) (1) and §1860D-4(a)(1)(A)]

Plan sponsors may provide materials using different media types (e.g., electronic or portable media like email, CD, or DVD). However, plan sponsors must receive consent prior to providing materials in this format (i.e., individuals must opt-in). When requesting consent, the plan sponsor must specify to the beneficiary the media type and the documents to be sent.

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: Requests for hard copies of plan web pages are excluded from this requirement.

- Inform members of the option and give them 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 and (opt-in) election 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, (e.g., an expired e-mail account).
- Have a system in place to monitor and evaluate the effectiveness of the electronic communication process.
- Ensure compliance with HIPAA.

40.13 - Standardization of Plan Name Type

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. Plan sponsors enter and maintain their plan names in the HPMS. Plan sponsors must include the plan type on all marketing materials when the plan name is mentioned.

To ensure the consistent use of standardized plan type terminology across all plan sponsors, the plan type label must be placed at the end of each plan name. For instance, an HMO plan named "Golden Medicare Plan" would appear as follows: "Golden Medicare Plan (HMO)."

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 be considered a model without modification.

50 - Marketing Material Types and Applicable Disclaimers

42 CFR 422.2264, 423.2264

In general, CMS groups marketing materials into two distinct categories – those materials directed to potential enrollees and communications to existing members. Unless otherwise noted, the disclaimers described in this section are required on all marketing materials created by the plan sponsor.

Disclaimers must be prominently displayed on the material and must be of similar font size and style (refer to § 40.2 for more information).

50.1 - Federal Contracting Disclaimer

42 CFR 422.2264, 423.2264

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

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.

- “[insert plan sponsor’s legal or marketing name] is a/an [insert plan type: HMO plan, PPO plan, PFFS plan POS plan, PSO plan] with a Medicare contract;”
- “[insert plan sponsor’s legal or marketing name] is a Medicare Advantage organization with a Medicare contract;”
- “[insert plan sponsor’s legal or marketing name] is a Health plan with a Medicare contract;”
- “[insert plan sponsor’s legal or marketing name] is a Federally-Qualified HMO with a Medicare contract;”
- “[insert plan sponsor’s legal or marketing name] is a Federally-Qualified Medicare contracting HMO;”
- “[insert plan sponsor’s legal or marketing name] is a Medicare-approved [insert plan type: HMO plan, PPO plan, PFFS plan, POS plan, PSO plan, Cost plan, MSA plan];” or
- “[insert plan sponsor’s legal or marketing name] is a Coordinated Care plan with a Medicare contract.”

NOTE: D-SNPs must add “and a contract with the [state] Medicaid program”.

PDP sponsors must use one of the following statements below, verbatim, either in the text of the piece or at the end/bottom 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.”

NOTE: Banner and banner-like ads, outdoor advertising, radio, television and Internet banner ads do not need to include the Federal contracting disclaimer.

50.2 - Disclaimers When Benefits Are Mentioned

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

The following disclaimers must be used when benefit information is included in marketing materials:

- “The benefit information provided is a brief summary, not a complete description of benefits. For more information contact the plan.”
- “Limitations, copayments, and restrictions may apply.”
- “[Benefits, formulary, pharmacy network, premium and/or co-payments/co-insurance] may change on January 1 of each year.”

50.3 – Disclaimers When Plan Premiums Are Mentioned

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

All plan materials that mention plan premium information must include the following disclaimer:

“You must continue to pay your Medicare Part B premium.”

NOTE: This statement is required even if the plan premium is \$0. This disclaimer is not required if the Part B premium is entirely paid by rebates under the plan. D-SNPs where the State pays the Part B premium should indicate that the Part B premium is covered for full-dual members.

50.4 – Disclaimer on Availability of Non-English Translations

42 CFR 422.2264, 423.2264

Plan sponsors that meet the five (5) percent threshold for language translation (Refer to § 30.7) must place the following alternate language disclaimer on all materials as required.

- “This information is available for free in other languages. Please contact our customer service number at [*insert customer service and TTY numbers, and hours of operation*].”

The alternate language disclaimer must 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 must be placed below the English version and in the same font size as the English version.

NOTE: ID cards are excluded from this requirement.

50.5 - SNP Materials

42 CFR 422.2, 422.4(a)(1)(iv), 422.111(b)(2)(iii), 422.2264, 423.2264

SNP plans must place a disclaimer related to enrollment eligibility on any materials targeting potential enrollees. Some examples are:

- “This plan is available to anyone with Medicare who meets the Skilled Nursing Facility (SNF) level of care and resides in a nursing home.”
- “This plan is available to anyone with Medicare who has been diagnosed with HIV/AIDS.”
- “This plan is available to anyone who has both Medical Assistance from the State and Medicare.”

Plan sponsors may only include the following information related to their NCQA SNP approval (See 30.3 for additional information):

- “[Insert Plan Name] has been approved by the National Committee for Quality Assurance (NCQA), a non-profit organization dedicated to improving health care quality [insert end date of NCQA approval].”

50.6 - Dual Eligible SNP Materials

42 CFR 422.2, 422.4(a)(1)(iv), 422.111(b)(2)(iii), 422.2264, 423.2264

The following disclaimer must be on any D-SNP materials targeting potential enrollees that mention cost-sharing information. The disclaimer is not required on materials for beneficiaries residing in the territories.

- “[premiums],[co-pays],[co-insurance], and [deductibles] may vary based on the level of Extra Help you receive. Please contact the plan for further details.”

50.7 –Private Fee For Service Plans

PFFS materials designed to target potential members must include the following disclaimer:

- “A Private Fee-for-Service plan is not a Medicare supplement plan. Providers who do not contract with our plan are not required to see you except in an emergency.”

50.8 –Medicare Medical Savings Accounts (MSAs)

MSA materials designed to target potential members must include the following disclaimers:

- “MSA Plans combine a high deductible Medicare Advantage Plan and a trust or custodial savings account (as defined and/or approved by the IRS). The plan deposits money from Medicare into the account. You can use this money to pay for your health care costs, but only Medicare-covered expenses count toward your deductible. The amount deposited is usually less than your deductible amount, so you generally have to pay out-of-pocket before your coverage begins.”
- “Medicare MSA Plans don’t cover prescription drugs. If you join a Medicare MSA Plan, you can also join any separate Medicare Prescription Drug Plan.”
- “There are additional restrictions to join an MSA plan, and enrollment is generally for a full calendar year unless you meet certain exceptions. Those who disenroll during the calendar year will owe a portion of the account deposit back to the plan. Contact the plan at [insert customer service and TTY] for additional information.”

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

42 CFR 422.2268, 423.2268

Plan sponsors that choose to enter into co-branding relationships with network providers are required to include the following disclaimer:

- “Other <Pharmacies/Physicians/Providers> are available in our network.”

50.10 - Disclaimer on Advertisements and Invitations to Sales/Marketing Events

42 CFR 422.2264, 423.2264

Advertisements and invitations to sales/marketing events (in any form of media) used to invite beneficiaries to attend a group session with the possibility of enrolling those individuals must include the following two statements on marketing materials:

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

50.11 - Disclaimer on Promoting a Nominal Gift

42 CFR 422.2268(b), 423.2268(b)

- Plan sponsors must include a written statement on all marketing materials promoting drawings, prizes or any promise of a free gift that there is no obligation to enroll in the plan. For example:
- “Eligible for a free drawing and prizes with no obligation.” or
- “Free drawing without obligation.”

50.12 – Disclaimer for Plans Accepting Online Enrollment Requests

42 CFR 422.2264, 423.2264

Plans accepting enrollment requests through the Online Enrollment Center (OEC), must state the following disclaimer on their websites:

“Medicare beneficiaries may also enroll in <plan name> through the CMS Medicare Online Enrollment Center located at <http://www.medicare.gov>.”

50.13 - Disclaimer When Using Third Party Materials

42 CFR 422.2264, 423.2264

CMS does not review materials developed by a third-party entity that is not affiliated or contracted with the plan sponsor. Plan sponsors choosing to provide marketing materials and/or services created by non-benefit/non-health service providing third-party entities must include the following disclaimer on all materials:

- “Medicare has neither reviewed nor endorsed this information”

The disclaimer must be prominently displayed at the bottom center of the first page of the material, or in the case of a website, on each page, and be a similar font size and style as the message.

In addition, any materials providing information on a subset of plan options and or services offered by a non-benefit/non-health service providing third-party entity must prominently display the following disclaimer on all materials.

- "This is not a complete listing of plans available in your service area. For a complete listing please contact 1-800-MEDICARE (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 all material (or 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 their membership. For further details on what CMS considers a non-benefit/non-health service providing third-party entity, please refer to § 40.11.3.

50.14 - Disclaimer When Referencing Plan Ratings Information

Plan sponsors must include the following disclaimer on all materials referencing Plan Ratings information:

"Plan performance Star Ratings are assessed each year and may change from one year to the next."

50.15 – Pharmacy Directory Disclaimers

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

50.16 – Mailing Statements

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 must prominently display one of the following four statements on the front of the envelope or if no envelope is being sent, the mailing itself. Plan sponsors may meet this requirement through the use of ink stamps or stickers,, 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 § 160.2 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.

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 or on the mailing when no envelope accompanies the mailer). 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 - Required Documents

60.1 - Summary of Benefits (SB)

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

The SB is a standardized document that should be generated via HPMS. Plan sponsors are required to include the SB when providing an enrollment form and also upon request. Additionally, plan sponsors must provide the multi-language insert any time they distribute an SB (see 30.7).

The SB allows beneficiaries to more easily compare the benefits offered by different plan sponsors and includes the following:

- Section (I): An introduction and the beneficiary information section, informing prospective enrollees of important aspects of enrolling in the plan.
- Section (II): A 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.
- Section (III): An optional free-form text area. This section is limited to six pages and can be used by plans to further describe special features of the program.
- Section (IV) or Medicaid Benefits: D-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);
 - The description of the benefits and cost-sharing protections that are covered under the D-SNP.

Plan sponsors must ensure that the language for sections I and II are 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 make the material non-compliant. Deviations include, but are not limited to, insertion of footnotes, plan specific clarifications, or format alterations, except as

indicated in the SB instructions. All sections of the SB must be submitted to CMS as one document under the File & Use process.

Plan sponsors must obtain any hard copy change request approval prior to submitting their SBs. Hard copy change requests must be submitted in HPMS using the SB Hard Copy Change module.

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. Plan sponsors can use a comparison matrix and still submit the document under File & Use. Plan sponsors must also modify Section I (introduction) to accurately reflect the plans that have been added to Section II.

NOTE: Annually, CMS will release technical specifications for the SB including global hard copy changes, requirements for specific plan types, and instructions for submission.

60.2 - ID Card Requirements

42 CFR 417.427, 422.111(i), 423.120(c)

All plan sponsors must issue and reissue (as appropriate) member identification cards that members may use to access covered services under the plan.

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.

Plan sponsors 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 or WEDI standard.

Combination health and drug plan ID cards must follow the NCPDP or WEDI standard and must include the required information in 6.2.1 and 6.2.2 below.

ID cards are not required to include:

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

(Refer to § 30.2 regarding co-branding requirements related to ID cards.)

60.2.1 – Health Plan ID Card Requirements

The health plan member identification card (for MA or 1876 cost plans) must comply with standards for medical ID cards in the most recent version of the Workgroup for Electronic Data Interchange (WEDI) *Health Identification Card Implementation Guide*.

Health plan ID cards must also include:

- The plan sponsor/plan website address.
- The plan sponsor’s customer service number.
- The phrase “Medicare limiting charges apply” (on PPO and PFFS cards only).
- The CMS issued Health Plan Identification Number (HPID)

60.2.2 – Part D ID Card Requirements

The Part D member identification card must comply with the most recent version of the National Council for Prescription Drug Program’s (NCPDP’s) “Pharmacy and/or Combination ID Card” standard. This standard is based on the American National Standards Institute ANSI INCITS 284-1997 standard titled Identification Card – Health Care Identification Cards.

The front of the Part D ID Card must include the Medicare Prescription Drug Benefit Program Mark (Refer to § 150 for more information.)

60.3 - Reserved

60.4 - Directories

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

Plan sponsors must send a Provider and Pharmacy Directory (as applicable) at the time of enrollment and at least every three years after that. Additionally, plan sponsors must make directories available upon request and ensure that websites contain current directories at all times.

MA, MAPD, Part D, and 1876 cost plan sponsors must include information regarding all contracted network providers and/or pharmacies in directories. Directories must include information about the number, mix, and distribution of network providers and/or pharmacies. Plans may have directories for each of the geographic areas they serve, (e.g., metropolitan areas, surrounding county areas), provided that all directories together cover the entire service area.

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 requirements to mail directories and post directories on their plan website.

Plan sponsors must make a good faith effort to provide written notice of termination of a contracted provider/pharmacy at least thirty (30) calendar days before the termination effective date to all members who regularly use the provider/pharmacy's services. This is true whether the termination was for or without cause. When a contract termination involves a primary care professional, all members who are patients of that primary care professional must be notified.

In instances where significant changes to the provider/pharmacy network occur, the organization must send a special mailing immediately. The requirement to send a special mailing for significant changes is in addition to other mailing timeframes. In general, plans can define "significant changes" when determining whether a special mailing is necessary. However, CMS may also determine if a mailing is needed and direct plans to conduct such a mailing.

See § 100 for additional website requirements.

60.4.1 - Pharmacy Directories

42 CFR 423.128(b)(5), 423.128 (c) (1)(E)

All Part D plans must include information regarding all contracted network pharmacies in their marketing materials provided at the time of enrollment and annually thereafter, as well as upon beneficiary request whichever occurs first (unless the plan sponsor uses changes pages as described in §

60.4). Part D sponsors must provide information about the number, mix, and distribution (addresses) of network pharmacies from which enrollees may reasonably be expected to obtain covered Part D drugs. Part D sponsors may have pharmacy directories for each of the geographic areas they serve (e.g., metropolitan areas, surrounding county areas) provided that all directories together cover the entire service area.

60.4.1.1 – Information about Pharmacies

- Information required in the pharmacy directory for non-chain pharmacies includes: pharmacy name, address, phone number, and type of pharmacy (e.g., retail, mail order, long-term care, home infusion/I/T/U).
- In lieu of providing the addresses for all locations of chain pharmacies, sponsors may provide a toll-free customer service number and a TTY number that an enrollee can call to get the locations and phone numbers of the chain pharmacies nearest to their home. If a chain pharmacy does not have a toll-free number, plan sponsors should include a central number for the pharmacy chain. If the chain pharmacy does not have a central number for enrollees to call, then plans must list each chain pharmacy location and phone number in the directory. If the chain pharmacy does not have a TTY number, plan sponsors are instructed to list the TRS Relay number 711. Plan sponsors should not list their own customer service number as a pharmacy phone number or TTY number.
- Part D sponsors must indicate which of their retail pharmacies provides an extended day supply of medications.
- Additionally, Part D sponsors must provide information that states the directory is current as of a particular date and that the pharmacy's listing in the directory does not guarantee the pharmacy is still in the network. Part D sponsors may indicate which of their network pharmacies support e-prescribing in their pharmacy directories. Model directories that include e-prescribing information will still be considered a model document without modification.

If a plan sponsor chooses to develop a non-model pharmacy directory, the directory must contain all information and follow all instructions within the CMS model pharmacy directory.

60.4.2 - Provider Directories

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

If a plan sponsor chooses to develop a non-model provider directory, the directory must contain all information and follow all instructions within the CMS model provider directory.

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

Plan sponsors may publish separate PCP and specialty directories provided both directories are given to enrollees at the time of enrollment and every three years from the enrollment date.

If a member has previously elected to receive a provider directory via another medium, (e.g., electronically), the plan sponsor may fulfill the requirement of mailing future directories through that medium, (e.g., e-mail).

NOTE: 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.

60.4.3 - Combined Provider/Pharmacy Directory

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; this is not considered a modification to the model, as long as no other changes are made.

60.5 - Formulary and Formulary Change Notice Requirements

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. 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 be displayed 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 be consistent.
- The applicable HPMS approved formulary file submission ID number, which is the HPMS formulary submission ID number of the approved formulary that is being marketed, and version number must be included.

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

42 CFR 423.128

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

- 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 <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 date the formulary was last updated and description of 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.
- 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); this is because many beneficiaries may only know the name of their prescription and not its therapeutic class.
- Explanation of any symbols or abbreviations used to indicate utilization management restrictions, drugs that are available via mail-order, excluded drugs, free first fill drugs, limited access drugs, drugs covered in the coverage gap, and drugs covered under the medical benefit (for home infusion drugs only).

60.5.2 - Comprehensive Formulary

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

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

comprehensive formulary by contacting the Part D plan. Drugs adjudicated at the point of sale as formulary drugs that are not found on the CMS approved HPMS formulary must be included in the comprehensive formulary. This may include drugs that are not found on the CMS approved HPMS formulary as described in § 60.5.

60.5.3 - Changes to Printed Formularies

42 CFR 423.128(a)-(c)

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, §§ 30.3.3.3 and 30.3.4.1. This requirement does not extend to mid-year maintenance changes defined in § 30.3.3.2 of Chapter 6 of the Prescription Drug Benefit Manual. Changes to previously printed formularies resulting from mid-year maintenance changes may be made at the time of the next printing. This is not a substitute for the required advance 60 days notice to affected beneficiaries.

60.5.4 - Other Formulary Documents

42 CFR 423.128(b)(4)

In addition to comprehensive and abridged formularies, Part D plans may choose to develop a formulary that lists all of their preferred drugs or is tailored to individuals with specific chronic conditions, as long as these items supplement the two required documents rather than replace them. The following disclaimer must also be displayed prominently on the cover of the document: "This is not a complete list of drugs covered by our plan. For a

complete listing, please call <Customer Service Phone and TTY Numbers/ > or visit <website address>.”

60.5.5 - Provision of Notice to Beneficiaries Regarding Formulary Changes

42 CFR 423.120(b)(5)

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

60.5.6 - Provision of Notice to Other Entities Regarding Formulary Changes

42 CFR 423.120(b)(5)

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

60.6 - Part D Explanation of Benefits

42 CFR 423.128(e)

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

If a plan sponsor chooses to develop a non-model EOB, the EOB must contain all information and follow all instructions within the CMS model.

NOTE: 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 2011 must be sent in January 2012, for December 2011 fills. Once the final EOB for CY 2011 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, 2011).

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

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

Except as outlined below, all plan sponsors must send the ANOC/EOC for member receipt by September 30 of each year. New Enrollees with an effective date of October 1, November 1, or December 1, should receive both an EOC for the current contract year and an ANOC/EOC for the upcoming contract year. New enrollees with an effective date of January 1 or later must receive an EOC for the contract year of coverage. Standalone EOC's do not need to be resubmitted in HPMS.

D-SNPs may choose to send the ANOC for member receipt by September 30 and the EOC for member receipt by December 31. D-SNPs that choose this option must also send an SB with the ANOC. D-SNPs that send a combined ANOC/EOC for member receipt by September 30 are not required to send an SB to current members.

Section 1876 cost plans offering Part D benefits must send the ANOC/EOC for member receipt by September 30 of each year. Section 1876 cost plans that do not offer Part D benefits must send the ANOC/EOC for member receipt by December 1 of each year.

Employer/union group plans must send the ANOC and EOCs for member receipt no later than fifteen (15) days before the beginning of the employer/union sponsor's open enrollment period (refer to Chapter 9 of the Medicare Managed Care Manual and Chapter 12 of the Prescription Drug Benefit Manual).

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 for each wave. For instructions on meeting this requirement, refer to the *Update Material Link/Function* section of the Marketing Review Users Guide in HPMS.

Plan sponsors must use the standardized ANOC/EOC errata model to correct any errors and must submit the errata model for review via HPMS. Plan sponsors must ensure corrected versions of the EOC are on their websites. Plan sponsors are not required to post the ANOC or the ANOC/EOC errata model on websites.

60.8 - Mid-Year Changes Requiring Enrollee Notification

42 CFR 422.111(d)(3)

When a National Coverage Determination (NCD) or legislative benefit change takes effect mid-year, MAOs and 1876 cost-based contractors must ensure access to the NCD item or service by furnishing or arranging for the service as of the effective date of the NCD or legislative benefit change. This requirement is applicable regardless of whether provider payment is the responsibility of the plan or Original Medicare, as described in detail in the Medicare Managed Care Manual, Pub 100-16, Chapter 4, section 90.4 (General Rules for NCDs). All NCDs are effective on the date the decision memorandum is released, (i.e., 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 change in coverage. If payment for the covered service is the responsibility of Original Medicare, the enrollee must be told that he or she can receive this service from any Medicare provider. Notifications must occur within 30 days of the release date of the NCD or legislative benefit change.

The plan sponsor may use a variety of mechanisms to inform enrollees of the change in coverage. At a minimum, the notice must be provided 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.

For more information on NCD and legislative benefit changes, please see Chapter 4 of the Medicare Advantage manual.

70 - Rewards and Incentives, Promotional Activities, Events, and Outreach

70.1 - Nominal Gifts

42 CFR 422.2268(b), 423.2268(b)

Generally, nominal gifts are used to attract the attention of potential enrollees. Plan sponsors may offer gifts to potential enrollee's as long as the gifts are of nominal value and provided regardless of enrollment. Nominal value is defined as an individual item/service worth \$15 or less (based on the retail value of the item).

The following rules must be followed when providing gifts:

- If a nominal gift is one large gift that is enjoyed by all in attendance (e.g., a concert), 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.
- Nominal gifts may not be in the form of cash or other monetary rebates. 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.

70.2 - Promotional Activities

42 CFR 422.2268, 423.2268

Generally, promotional activities are those designed to attract the attention of prospective members and/or encourage retention of current members. In addition to the guidance on nominal gifts (refer to 70.1), any promotional activities or items offered by plan sponsors:

- Must be worth \$15 or less with a maximum aggregate of \$50 per person, per year;
- Must be offered to all people regardless of enrollment and without discrimination;

- Must not be items that are considered a health benefit, (e.g., a free checkup);
- Must not consist of lowering or waiving co-pays;
- Must not be used or included with the SB, ANOC/EOC;
- Must not inappropriately influence the beneficiary's selection of a provider, practitioner, or supplier of any item or service.
- Must be tracked and documented during the contract year; and
- Must not be tied directly or indirectly to the provision of any other covered item or service.

Note: Plan sponsors must track and document items given to current members. Plan sponsors are not required to track pre-enrollment promotional items on a per person basis; however, they may not willfully structure pre-enrollment activities with the intent to give people more than \$50 per year.

70.3 - Rewards and Incentives

42 CFR 422.2268, 423.2268

Rewards and incentives may only be offered to current members for Medicare covered preventive services that have a zero dollar cost-share. Please see below for links to information about Medicare covered preventive services at zero dollar cost-share. Plan sponsors are not bound by the \$50 maximum when structuring reward and incentive programs.

Reward and incentive items must:

- Be offered in connection with the whole service, (e.g., a plan sponsor may offer a reward for participating in the smoking cessation program but not offer multiple awards for attending each smoking cessation class.);
- Be offered to all eligible members without discrimination;
- Have a monetary cap not to exceed \$15 per reward item (based on the retail value of the item)
- Be tracked and documented during the contract year;

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

Additionally, reward and incentive items cannot:

- Be items that are considered a health benefit, (e.g., a free checkup);
- Be items that consist of lowering or waiving co-pays;
- Be offered in the form of cash or other monetary rebates;
- Be used to target potential enrollees (e.g., used in pre-enrollment advertising, marketing, or promotion of the plan);
- Be structured to steer enrollees to particular providers, practitioners, or suppliers; and
- Be tied directly or indirectly to the provision of any other covered item or service.

Please refer to the resources below for the most current listing of Medicare covered preventive services with a zero dollar cost-share.

- Coverage email updates page, sorted by year - <https://www.cms.gov/CoverageGenInfo/EmailUpdates/list.asp#TopOfPage>
- Main Coverage Center page - <https://www.cms.gov/center/coverage.asp>
- Sign-up for the coverage listserv - https://www.cms.gov/InfoExchange/03_listserv.asp#TopOfPage
- Program Transmittals page - <http://www.cms.gov/Transmittals/>

70.4 - Exclusion of Meals as a Nominal Gift

42 CFR 422.2268(p), 423.2268(p)

Plan sponsors may not provide meals (or have meals subsidized) at sales/marketing events.

Plan sponsors are, however, allowed to provide refreshments and light snacks. 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 § 70.1.

70.5 - Unsolicited E-mail Policy

42 CFR 422.2268(d) 423.2268(d)

A plan sponsor may not send e-mails unless an individual has agreed to receive those e-mails. 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 individuals at e-mail addresses obtained through friends or referrals.
- Plan sponsors must provide an opt-out process to no longer receive e-mail communications.

70.6 - Marketing through Unsolicited Contacts

42 CFR 422.2268(d), 423.2268(d)

In general, plan sponsors may not market through unsolicited contacts; including but not limited to:

- Door-to-door solicitation, including leaving information such as a leaflet or flyer at a residence or car.
- Approaching beneficiaries in common areas, (e.g., parking lots, hallways, lobbies, sidewalks, etc.)
- Telephonic or electronic solicitation, including leaving electronic voicemail messages or text messaging.

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).

In addition, permission given to be called or otherwise contacted must be event-specific, and may not be treated as open-ended permission for future contacts.

70.7 - Telephonic Contact

42 CFR 422.2268(d), 423.2268(d)

Agents may contact their own clients and plan sponsors may contact current members at anytime to discuss plan business. Prohibited telephonic activities include, but are not limited to, the following:

- Bait-and-switch strategies - making unsolicited calls about other business as a means of generating leads for Medicare plans.
- Calls based on referrals. 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 individual needs to contact the plan or agent/broker directly.
- Calls to former members who have disenrolled, or to current members who are in the process of voluntarily disenrolling (except as permitted below), to market plans or products. 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 documentation of permission to be contacted).
- 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.
- 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.

- Contact members to promote other plan types, (e.g., sponsors may contact their PDP members to promote their MA-PD 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 individuals 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 individual 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 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.

70.8 - Outbound Enrollment and Verification Requirements

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 both independent and employed agents/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 those 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 conduct these outbound calls; CMS expects OEV calls to be interactive.

The following agent/broker-effectuated enrollments are excluded from the OEV requirement:

- Enrollments into employer or union sponsored plans
- Plan-to-plan switches within a parent organization involving the same plan type or product type (e.g., PFFS to PFFS, D-SNP to D-SNP, PDP to PDP).

Plan sponsors must make a minimum of three documented attempts to contact the applicant by telephone within fifteen (15) calendar days of receipt of the application; the first two attempts must be made within the first 10 days. If the enrollment application is incomplete, plan sponsors should concurrently conduct the OEV process while obtaining the missing information needed to complete the application.

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 does not have all the information required to complete the enrollment process at the time of the OEV call, the sponsor should obtain that information during the call. 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 but must resume if the sponsor determines the rejection to be erroneous, such that the enrollment will be resubmitted to CMS.

Plan sponsors that do not successfully reach the beneficiary on the first or second attempt must send the applicant an enrollment verification letter in addition to making the third documented outbound verification call attempt within the 15 day timeframe.

70.9 - Educational Events

42 CFR 422.2268(I), 423.2268(I)

An educational event is an event designed to inform Medicare beneficiaries about Medicare Advantage, Prescription Drug or other Medicare programs and does not include marketing, (i.e., the event sponsor 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. These events cannot be held at in-home or one-on-one settings.

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.

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.

Materials distributed or made available at an educational event must be free of plan-specific information, (including plan-specific premiums, co-payments, or contact information), and any bias toward one plan type over another.

The following are examples of acceptable materials and activities by plan sponsors or their representatives at an educational event:

- A banner with the plan name and/or logo displayed.
- 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.
- Respond to questions asked at an educational event.

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 individual sales appointments or get permission for an outbound call to the beneficiary.
- Attach business cards or plan/agent contact information to educational materials, unless requested by the beneficiary.
- Advertise an educational event and then have a marketing/sales event immediately following in the same general location, (e.g., same hotel).

NOTE: If plan sponsors hold member-only events, they may not conduct enrollment or sales activities at these events. Additionally, any marketing of these events must be done in a way that reasonably targets only existing members, (e.g., direct mail flyers), and not the mass marketplace, (e.g., radio or newspaper ad).

70.10 - Marketing/Sales Events

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 and collect applications.

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.

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.

- Plan sponsors must submit all sales scripts and presentations for approval to CMS prior to their use during the marketing/sales event.

At a marketing/sales event, plan sponsors may not:

- Conduct health screening or other like activities that could give the impression of "cherry picking."

- 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.
- Use personal contact information obtained to notify individuals of raffle or drawing winnings for any other purpose.

70.10.1 – Notifying CMS of Scheduled Marketing Events

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. Plan sponsors have the option to upload educational events. 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: Plan sponsors should not enter Employer Group Health Plan (EGHP) events that are only for EGHP members into HPMS.

While CMS recognizes that plan sponsors may have last minute events scheduled and will permit these events to be uploaded into HPMS. CMS expects that at least 90% of all formal and informal events will be uploaded at least seven (7) calendar days prior to the event's schedule date.

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 and room changes), should 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. Plan sponsors should notify

beneficiaries of event cancellations according to the following requirements. (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.

NOTE: 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:
 - Notify its Regional Office Account Manager of the cancellation and cancel the event in HPMS.
 - Notify beneficiaries of the cancellation by the same means the plan sponsor used to advertise the event. A representative is not required to be present at the site.

Example of reasonable notification:

If an announcement of the sales event was made in the newspaper, then it is reasonable to announce the cancellation through the same newspaper.

70.10.2 - Personal/Individual Marketing Appointments

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 § 70.10.3).

All one-on-one appointments with Medicare beneficiaries are considered sales/marketing events. However, one-on-one appointments are not entered into the marketing events module.

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

- Discuss plan options that were NOT agreed to by the Medicare beneficiary.
- Market non-health care related products (such as annuities or life insurance).
- 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 another enrollment period.

70.10.3 - Scope of Appointment

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

In conducting marketing activities, a 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 (48-hours in advance when practicable).

NOTE: Marketing/sales events, as defined in § 70.10, do not require documentation of beneficiary agreement.

The sales person is bound to only discuss those products that have been agreed upon by the beneficiary during that appointment; distinct lines of plan business include MA and PDP products. If other products need to be discussed at the request of the beneficiary, a second scope of appointment must be documented for the new product type and then the marketing appointment may be continued.

To further clarify the requirements around documentation:

- The documentation can be in writing, in the form of a signed agreement by the beneficiary, or a recorded oral agreement. 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 set a scope of appointment at a marketing/sales event for a future appointment.

NOTE: All business reply cards (BRC) used for documenting beneficiary scope of appointment or agreement to be contacted must be submitted to CMS.. Additionally, plan sponsors should include a statement on the BRC informing the beneficiary that a sales person may call as a result of their returning a BRC.

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

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

In instances where a beneficiary visits a plan or an agent/broker office on his/her own accord, the plan sponsor or agent/broker must document the scope of appointment prior to discussing MA, PDP, or cost plans.

70.11 - PFFS Plan Provider Education and Outreach Programs

42 CFR 422.114(a)(1)

PFFS plan sponsors must conduct effective outreach to providers to help them understand how PFFS plans work and to overcome any resistance that may be particularly caused by concerns about the timeliness and accuracy of payments. They must ensure that they clearly inform providers about how to obtain their terms and conditions of payment, how to get payment or coverage questions quickly answered, and how to appeal payment decisions.

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

42 CFR 422.114

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

“PFFS Terms and Conditions of Payment Contact for Public website” field should be populated with the contact that will facilitate provider access to the MAO’s PFFS plan terms and conditions of payment. Use the following navigation path in HPMS to enter the appropriate information for this new contact: HPMS Homepage > Contract Management > Contract Management > Select a Contract Number > Contact Data.

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

70.12 - Marketing in the Health Care Setting

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

Plan sponsors and providers who they have a relationship with, (contract or otherwise), that assist beneficiaries with plan selection should 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.

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.

Plan sponsors are only permitted to schedule appointments with beneficiaries residing in long-term care facilities (including nursing homes, assisted living facilities, board and care homes, etc.) upon request by the beneficiary. 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 such as the provider's waiting room. Additionally, long-term care facilities are permitted to provide materials 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.

70.12.1 - Provider-Based Activities

42 CFR 422.2268(j), 423.2268(j)

CMS is concerned with provider marketing activities for the following reasons:

- Providers may not be fully aware of all plan benefits and costs
- 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

To the extent that a provider can assist a beneficiary in an objective assessment of his/her needs and potential options to meet those needs, they may do so. Providers may engage in discussions with beneficiaries should a beneficiary seek advice. However, providers must remain neutral when assisting with enrollment decisions and may not:

- Offer sales/appointment forms.
- Accept Medicare enrollment applications.
- Make phone calls or direct, urge or attempt to persuade beneficiaries to enroll in a specific plan based on financial or any other interests of the provider.
- Mail marketing materials on behalf of plan sponsors.

- Offer anything of value to induce plan enrollees to select them as their provider.
- Offer inducements to persuade beneficiaries to enroll in a particular plan or organization.
- Conduct health screening as a marketing activity.
- Accept compensation directly or indirectly from the plan for beneficiary enrollment activities.
- Distribute materials/applications within an exam room setting.

Providers may:

- Provide the names of plan sponsors with which they contract and/or participate (See § 70.12.2 for additional information on affiliation).
- Provide information and assistance in applying for the LIS.
- Make available and/or distribute plan marketing materials.
- 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.
- Share information with patients from CMS' website, including the "Medicare and You" Handbook or "Medicare Options Compare" (from <http://www.medicare.gov/>), or other documents that were written by or previously approved by CMS.

70.12.2 - Provider Affiliation Information

42 CFR 422.2268, 423.2268

Providers may announce new or continuing affiliations for specific plan sponsors through general advertising, (e.g., radio, television, websites). New affiliation announcements are for 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 a list of 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 prior to use for each plan sponsor mentioned. Materials that indicate the provider has an affiliation with certain plan sponsors and that only list plan names and/or contact information do not require CMS approval.

70.12.3 - SNP Provider Affiliation Information

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.

70.12.4 - Comparative and Descriptive Plan Information

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).

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

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/non-health service providing third party providers, refer to § 40.11.3.

70.12.6 - Providers/Provider Group Websites

42 CFR 422.2268, 423.2268

Provider websites may provide links to plan enrollment applications and/or provide downloadable enrollment applications. If providers permit links/downloadable access to plan enrollment applications on their websites, they must permit all plan sponsors upon request to have links/downloadable access in their websites. As an alternative, providers may include a link to the CMS Online Enrollment Center.

NOTE: Medicare MSAs, 800-series employer group waiver plans, and Religious Fraternal Benefit plans are excluded from this requirement.

80 - Telephonic Activities and Scripts

80.1 - Customer Service Call Center Requirements

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

Plan sponsors must operate a toll-free call center for both current and prospective enrollees 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. Plan sponsors may use alternative technologies on Thanksgiving and Christmas Day. 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.

NOTE: From February 15 to September 30, plan sponsors may use alternative technologies on Saturdays, Sundays, and Federal holidays.

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 and hearing impaired beneficiaries.
- Inform callers that interpreter services are “free.”
- Limit average hold time to two (2) minutes. The average hold time is defined as the time spent on hold by the caller following the interactive voice response (IVR) system, touch tone response system, or recorded greeting and before reaching a live person.
- Answer eighty (80) percent of incoming calls within thirty (30) seconds.
- Limit the disconnect rate of all incoming calls to five (5) percent.

For Pharmacy Technical Help or Coverage Determinations and Appeals Call Center requirements refer to Appendix 5.

80.2 - Expectations for Scripts

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

Generally speaking, CMS categorizes scripts as either informational in nature or related to sales/enrollment. Informational scripts are those designed to respond to beneficiary questions and requests and provide objective information about the plan and Medicare program. Sales and enrollment scripts are those intended to steer a beneficiary towards a plan or limited number of plans and those used to enroll a beneficiary into a plan.

Plan sponsors are only required to enter sales/enrollment scripts into HPMS; however, they must retain all other scripts and make them available upon CMS request. CMS expects sponsors to incorporate in their scripts all relevant requirements outlined in these Medicare Marketing Guidelines (e.g., hours of operation, TTY number, etc.).

At a minimum, plan sponsors must develop scripts that respond to inquiries from prospective and current enrollees about the following subjects:

- Best Available Evidence (BAE) policy
- Request for pre-enrollment information
- Benefit information
- Cost-sharing information

- Formulary information
- Pharmacy information, including whether a beneficiary's pharmacy is in the plan sponsor's network
- Provider information, including whether a beneficiary's physician is in the plan sponsor's network
- Out-of-network coverage
- Claims submission, processing and payment
- Formulary transition process
- Grievance, coverage determination (including exceptions) and appeals process
- Information on extra help, including how the beneficiary can obtain extra help
- Current TROOP status
- Information on how to obtain needed forms
- Information on replacing a member identification card
- Service area information

80.3 – Requirements for Informational Scripts

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

Informational scripts may not ask the beneficiary if s/he wants to be transferred to a sales/enrollment department nor can the plan sponsor's call center staff automatically transfer the call. CMS recognizes that, in some instances, a beneficiary may initiate a request for information and subsequently request enrollment into a plan. CMS expects that informational calls will only lead to sales/enrollment calls (or transferred to the appropriate sales/enrollment department) at the proactive request of the beneficiary.

Example: A beneficiary calls customer service and requests to hear information about a particular plan. Based on the information provided, the beneficiary states that s/he wants to enroll in the plan. The customer service representative may process the enrollment

and/or transfer the call to the appropriate area for processing because the beneficiary initiated the request.

Any change in the nature of a call from informational to sales/telephonic enrollment must clearly inform the beneficiary regarding the change. This must be done with the full and active concurrence of the beneficiary, ideally with a yes/no question.

Plan sponsors may NOT:

- Include information about other lines of business in scripts.

NOTE: Plan sponsors can ask if the caller would like to receive information about other lines of business offered by the plan sponsor.

- Request beneficiary identification numbers (e.g., Social Security number, bank account numbers, credit card number, HICN) except as required to verify membership, determine enrollment eligibility or process an enrollment request).
- 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.

NOTE: Plans may not transfer outbound calls to inbound lines for telephone enrollment.

80.4 - Requirements for Enrollment Scripts/Calls

42 CFR 422.60 (c), 423.32 (b)

Telephone enrollment scripts must be submitted in their entirety (bullets or talking points are not acceptable). In developing and submitting enrollment scripts plan sponsors must:

- Follow all guidance and requirements described in the CMS Eligibility and Enrollment Guidance in Chapters 2 and 17d of the Medicare Managed Care Manual and Chapter 2 of the Medicare Prescription Drug Benefit Manual.
- Clearly state the individual is requesting enrollment into [plan name] and the plan type.

- Provide confirmation of having accepted the telephone enrollment request, such as a confirmation tracking number or other tracking mechanism.
- Provide 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.
- Provide contact information for questions including toll-free telephone and TTY numbers.

NOTE: Plans may not conduct outbound telephonic enrollment except as required to perform outbound education and verification calls (refer to §70.8)

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

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

Any telephone sales scripts must be submitted verbatim (bullets or talking points are unacceptable). Plans must follow all telephone guidance in marketing through unsolicited contacts as noted in §§ 70.5 and 70.6. This guidance extends to all downstream contractors.

In addition, 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.

Sales calls 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.

90 - The Marketing Review Process

90.1 - Plan Sponsor Responsibilities

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

Plan sponsors are responsible for conducting a quality check and ensuring that all materials are consistent with this chapter and all other relevant CMS issued guidance and instructions prior to submitting materials for review to CMS. Generally, CMS does not review marketing materials for typographical

or grammatical errors, unless such errors render the marketing materials inaccurate or misleading.

90.2 - Material Submission Process

42 CFR 422.2262, 423.2262

Plan sponsors are required to submit materials for review through the Marketing Module of the HPMS, which is an automated tool used to enter, track, and maintain marketing materials submitted to CMS for review and approval. The HPMS Marketing Module User Guide provides extensive information on how to use HPMS.

If there are any changes or corrections to materials, (e.g., 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 within a reasonable timeframe. If CMS finds that the sponsor failed to comply with applicable rules and guidance, we may take compliance action, including intermediate sanctions and civil money penalties.

Under extraordinary circumstances, and with prior approval from CMS, marketing materials may be submitted outside of HPMS. The review period begins when CMS receives the materials.

90.2.1 - Submission of Non-English Materials or Alternative Formats

42 CFR 422.2264 (e), 423.2264(e)

Non-English materials must be based on previously approved English versions of the same material. Materials submitted as an alternate format material may be used immediately.

Any changes or revisions that are made to the English version should be accurately reflected in non-English materials and re-submitted as required.

90.2.2 - Submission of Websites for Review

42 CFR 422.2262, 423.2262

Plan sponsors must submit all MA, 1876 cost plan, and PDP websites for review. Plan sponsors should submit their websites via links in a Word document. 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 via links on a Word document. Any updates to pages should be submitted with their own unique material ID and date stamped accordingly.

Plan sponsors may make the website available for public use during the CMS review period; however, plan sponsors must include the status *pending* on their website until CMS has granted final approval/disapproval. Use of the website while under CMS review applies only to the website text and not documents contained on the website, (e.g., a plan may not post an unapproved member handbook on the website).

If any portion of a plan sponsor's website is disapproved, the plan sponsor must remove the disapproved portion immediately.

See § 100 for required website content.

90.2.3 – Service Area/Low Income Subsidy Materials Functionality (SA/LIS) - Multiple Submissions of Materials

42 CFR 422.2262, 423.2262

HPMS restricts multiple submissions of materials that have a "Y" in the plan designation column on the marketing code look-up listing in HPMS. (Refer to the marketing code look-up in HPMS.) After the initial submission, the plan should use the SA/LIS functionality to upload additional versions of the material and change the status of the material when uploading from "pending" to "additional SA/LIS submission". For example, if a PDP edcovers two states, the PDP sponsor would submit the EOC for one of the States as the initial submission and then use the SA/LIS functionality to submit the EOC for the second state. Similarly, a plan that has different versions of the EOC based on dual eligibility status would use the functionality to submit the other versions.

90.2.4 – Submission of Multi-Plan Materials

42 CFR 422.2262, 423.2262

Multi-Plan Materials are those materials that are created by a third party entity on behalf of several plan sponsors (e.g., a PBM who creates a Part D EOB that will be used by multiple plan sponsors). Plan sponsors must follow these procedures when submitting multi-plan marketing materials on behalf of a third party entity. Plan sponsors will be held accountable for the marketing practices of their third party organizations and must ensure that all materials developed on their behalf are compliant with CMS marketing requirements.

Relevant terms for this process include:

- **Primary Material** -- The base marketing material that serves as a model for submission by multiple plan sponsors.
- **Auxiliary Material** -- The secondary marketing materials developed based on the CMS-approved Primary Material.
- **Coordinating Entity (CE)** -- The third party entity that develops the Primary Material for use by the plan sponsors with which it contracts.
- **Lead Plan Sponsor (LP)** -- Contracted plan sponsor that submits the Primary Material for CMS review.
- **Non-Lead Plan Sponsor (NLP)** -- Contracted plan sponsor that produces and submits to CMS the Auxiliary Material, based on the approved Primary Material.

The Coordinating Entity (CE) develops marketing materials in accordance with CMS requirements and coordinates with the Lead Plan (LP) to obtain CMS' approval on multi-plan marketing materials (the CMS Lead Region will be the region that has account management oversight and marketing review of the LP). The LP will inform the CE of approval who then communicates to all Non-Lead Plans (NLPs) the material ID and original submission code so they may upload the multi-plan material in HPMS. Communications should occur via email for tracking and documentation purposes.

The LP must insert the following in the comments field:

- "MULTIPLAN MARKETING MATERIAL PRIMARY". This standardized text must be inserted in the first line of the comments field.
- The name and role of the CE who created the material (e.g., ABC FMO or XYZ PBM) must be inserted in the second line of the comments field.

- A list of all MCE or contract numbers for which the material is applicable.
- Any applicable information related to the piece that will assist CMS with the review.

The material ID for multi-plan marketing materials is made up of four parts. The first part of the material identification number is the plan sponsors' contract number. The second part of the identifier must be the word "MULTIPLAN". The third part of the identifier is any series of alpha numeric characters chosen at the discretion of the plan sponsor. The fourth part includes either the term "Approved" or the term "Accepted," as appropriate.

If a material is disapproved, CEs must resubmit disapproved pieces through the same LP. Prior to submitting in HPMS, plans must employ consistency checks and internal controls to ensure materials meet CMS requirements. Any disapproval of multi-plan marketing materials is subject to impact the LPs disapproval threshold and may result in compliance action.

When a NLP receives direction from a CE that a multi-plan "Primary" material has been approved/accepted, the NLP should upload the "Auxiliary" material in HPMS using the same category that was selected for the "Primary" material. All NLPs must submit the previously approved/accepted piece WITHOUT MODIFICATION except as allowable by CMS. Permissible modifications are restricted to populating variable elements and adding a plan name/logo.

When submitting, the NLP must insert the following in the comments field:

- "MULTIPLAN MARKETING MATERIAL AUXILLARY". This standardized text must be inserted in the first line of the comments field.
- The name and role of the CE who created the material.
- A brief description of the material's previous submission history, including the "Primary" material ID (e.g., This Multiplan website was previously approved by CMS on Month/Day/Year. It was initially submitted by ABC123 Health Care under material ID [x].).

The NLP must use the material ID of the previously approved/accepted "Primary" material.

NLP multi-plan marketing materials submitted for CMS review may not be used in the market place until approval from a plans' CMS reviewer is

received. Materials submitted File & Use may not be distributed until the five calendar waiting period has passed.

NOTE: There may be instances where a CE wants to use a material for a plan not identified in the original LP submission (e.g., if the CE solidifies a contract with a new plan sponsor). A material may be submitted for a plan not identified in the original submission. To do so, the NLP should submit the material and provide an explanation in the comments of HPMS for why it was not listed in the initial listing of contract numbers (e.g., they were not contracted with the CE during the initial submission). The name, phone, and email contact of the CE should also be included

90.3 - Material Dispositions

42 CFR 422.2262, 423.2262

For all marketing materials submitted for review by CMS, one of the following dispositions will be rendered - approved, disapproved, deemed, or withdrawn.

90.3.1 - Approved Disposition

42 CFR 422.2262, 423.2262

CMS approval of a material submission indicates that it is approved for use in the format in which it was submitted and may be distributed by a plan sponsor. However, CMS may at any time require a plan sponsor to change any previously approved marketing materials if found to be inaccurate, altered, or otherwise non-compliant.

NOTE: Prior to having an executed contract with CMS, plan sponsors' marketing material dispositions will be considered "conditionally" approved.

90.3.2 - Disapproved Disposition

42 CFR 422.2262, 423.2262

CMS disapproval of a material submission indicates that the material does not comply with the MMG, or with applicable regulations, laws, or other relevant guidance. CMS will provide a reason for the disapproval generated in HPMS.

90.3.3 - Deemed Disposition

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

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

- Materials subject to a forty-five (45) day review period will be given the status of “Deemed” on the forty-sixth (46th) day.
- Materials subject to a ten (10) day review period will be given a status of “Deemed” on the eleventh (11th) day.
- Plan sponsors that do not have a final contract will receive a conditional deemed approval. After the contract is awarded, the materials disposition will be changed to “Deemed” and can then be used.

The status of “Deemed” means that a plan sponsor may use the material. Plan sponsors should include [Deemed] and follow the marketing material identification system described in § 40.1.

90.3.4 - Withdrawn Disposition

42 CFR 422.2262, 423.2262

A plan sponsor can request to withdraw a marketing submission prior to CMS acting upon that marketing submission, (e.g., prior to beginning its review). Plan sponsors should submit a written request to their CMS Regional Office Account Manager or Marketing Reviewer stating the reason(s) for the withdrawal.

90.4 - Resubmitting Previously Disapproved Pieces

42 CFR 422.2262, 423.2262

To expedite the review of previously disapproved pieces, plan sponsors must clearly indicate all changes/updates made to a material when it is resubmitted. Plan sponsors may meet this requirement by highlighting any text changes and/or inserting notes to altered areas on the material. Plan sponsors may develop an alternative process for identifying changes, (e.g., bulleting all changes made within the comments section of HPMS when submitting the material), provided they discuss alternatives with and receive approval from the Account Manager.

90.5 - Time Frames for Marketing Review

42 CFR 422.2262(a) 423.2262(a)

Based on the material type, and as indicated by HPMS, marketing materials submitted for prospective CMS review will have a review timeframe of 10 or 45 days. The marketing review time period begins on the date a material is submitted to HPMS. If on the 11th or 46th day (as applicable) a decision has not been rendered by CMS, the material will be “deemed” approved.

The review period restarts each time an individual marketing material is submitted to CMS for review.

90.6 - File & Use Program

42 CFR 422.2262(b), 423.2262(b)

Plan sponsors using the File & Use process must submit File & Use eligible marketing materials to CMS at least five (5) calendar days prior to distribution and certify that the materials comply with this chapter.

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

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

- In order to use the File & Use program, the plan sponsor must submit the File & Use certification form (refer to Model File & Use Certification form, Appendix 3) to its appropriate CMS Regional Office before it may submit File & Use materials. The requirement for submission of a signed certification form is a one-time only requirement; the signed certification is effective until further notice.
- Plan sponsors that do not submit the File & Use certification form are considered ineligible to submit documents as File & Use. In this instance, any such submissions would be subject to compliance actions.

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 use the File & Use program.

- The PDP sponsor may submit File & Use materials prior to executing a contract with CMS. 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.

90.6.1 - Restriction on the Manual Review of File & Use Eligible Materials

42 CFR 422.2262(b), 423.2262(b)

Plan sponsors that choose to utilize File & Use must submit at least ninety (90) percent of marketing materials that qualify for File & Use under this process. More specifically, plan sponsors choosing to utilize File & Use should request a manual review of no more than ten (10) percent of materials that qualify for File & Use (including, but not limited to model materials that qualify for File & Use submission). CMS will continue to monitor compliance with this requirement.

90.6.2 - Loss of File & Use Certification Privileges

42 CFR 422.2262(b), 423.2262(b)

A plan sponsor may lose File & Use Certification status or face compliance action if it:

- Uses materials that do not meet the requirements of this chapter;
- Fails to file material(s) at least five (5) calendar days prior to distribution or publication; or
- Is found 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 the MMG.

If CMS revokes a plan sponsor's File & Use Certification privileges, the plan sponsor may be reinstated after the Account Manager and/or Marketing Reviewer has determined through manual review that the compliance concerns have been resolved.

90.6.3 - File & Use Retrospective Monitoring Reviews

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.

90.7 - Model Materials

42 CFR 422.2262 (c), 423.2262 (c)

CMS has developed certain model materials that are optional for use by plan sponsors; these are considered non-standardized model materials. Plan sponsors that choose to modify the model language must ensure that all elements provided in the model are included in the non-model document. Model documents modified by the plan sponsor are subject to a forty-five (45) day review period. Generally, model documents used without modification will result in a ten (10) day marketing review period or may be submitted via File & Use.

“Without modification” means the plan sponsor used CMS model language verbatim except where indicated and allowed by CMS, (e.g., variable fields). To facilitate review, plan sponsors must indicate the model/exhibit title and applicable CMS chapter/manual or HPMS memorandum date within the comments section of HPMS.

The following allowable alterations to CMS model materials will still render the material eligible for the ten (10) day review period or submission via File & Use:

- Populating variable fields,
- Adding fields to populate with a name and address,
- Correcting grammatical errors,
- Changing the font,
- Adding any applicable disclaimers,
- Adding the customer service phone number where references are made to call customer service,
- Adding the plan name/logo,
- Adding a table of contents or index to the pharmacy/provider directory, 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. 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.

NOTE: D-SNPs may remove references to LIS from CMS model materials.

90.7.1 - Standardized Language

42 CFR 422.2262 (c), 423.2262 (c)

Standardized language refers to language developed by CMS which is mandatory for use by plan sponsors and cannot be modified in any way.

90.7.2 - Required Use of Standardized Model Materials

42 CFR 422.2262 (c) , 423.2262 (c)

Standardized model materials are model documents that a plan sponsor must use without changing the content, format, or order. CMS allows plan sponsors to make the following changes to standardized models:

- Populating variable fields,
- Correcting grammatical errors,
- Adding the customer service phone number where references are made to call customer service,
- Adding the plan name/logo, and
- Adding the CMS marketing material identification number.

90.8 - Template Materials

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.

Plan sponsors should submit template materials using one “master document.” Plan sponsors must show how the placeholders in template materials will be populated by inserting the name of the field or listing all variables (e.g., “<date>”, “<\$10.00 Copay/\$15.00 Copay>”).

Populated standard templates must be submitted within thirty (30) days of use. Plan sponsors are responsible for submitting final, populated versions of templates (except static 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. If there are any changes or corrections to final materials, (e.g., 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.

90.8.1-Standard Templates

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. 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.

Materials with variable placeholders 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.

90.8.2-Static Templates

42 CFR 422.2262, 423.2262

A static template is a marketing material that includes placeholders for variable data fields that can be submitted in HPMS via File & Use and do not have to be resubmitted once they are populated. In order to be considered a static template, ALL variable data fields within the material must be exempt from resubmission in HPMS as noted below. Since static templates are not resubmitted, plan sponsors should not indicate that the “master” document is a template when submitting the material in HPMS.

The following variable data fields are exempt from the template resubmission 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
- Photos
- Email addresses and web addresses
- LIS Rider

90.8.3 - Template Materials Quality Review and Reporting of Errors

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

CMS may conduct retrospective reviews, quality checks, or audits of populated templates. When errors are discovered, a plan sponsor must report the errors to its Account Manager. In addition, plan sponsors may be required to remedy the error by providing beneficiaries with updated information via errata sheets or addenda.

NOTE: Any materials, such as errata sheet or addenda, must be reviewed and approved by CMS prior to their use.

90.9 - Review of Materials in the Marketplace

42 CFR 422.2268, 423.2268

CMS periodically conducts reviews of plan sponsor materials. Reviews could include, but are not limited to, the following activities:

- Review of on-site marketing facilities, products, and activities during regularly scheduled contract compliance monitoring visits.
- Random review of actual marketing pieces as they are used in the marketplace.
- “For-cause” review of materials and activities when complaints are made by any source, and CMS determines it is appropriate to investigate.
- “Secret shopper” activities where CMS requests plan sponsor materials such as enrollment packets.

100 - Plan Sponsor Websites and Social/Electronic Media

42 CFR 422.111(h), 423.128(d)

Plan sponsors must maintain their current contract year website for beneficiaries through December 31 of each year. They may not include website content for the next contract year prior to October 1.

All plan sponsor websites must be clear and easy to navigate. Any marketing materials that include a web address for the sponsor’s website must link directly to the organization’s Medicare specific pages.

Plan sponsors must post materials needed to make an informed decision (e.g., SB) in such a manner as to allow beneficiaries the ability to read them prior to accessing an enrollment form.

Plan sponsor websites must not provide links to foreign drug sales.

Plan sponsors are allowed to use social/electronic media, (e.g., Facebook, Twitter, Scan Code, or QR Code). However, such tools are still considered marketing materials and subject to these guidelines.

100.1 - General Website Requirements

All plan sponsor websites must:

- Maintain a separate and distinct section of their website for Medicare information if the plan sponsor markets other lines of business.
- Post all required disclaimers in § 50.
- Include the plan's toll-free customer service number and hours of operation, TTY number, and either a physical address or Post Office Box.
- Include the status *pending* until CMS has granted an approval/disapproval (Refer to 90.2.2).
- If there is a link on the sponsor's website that will take an individual to non-Medicare information the individual must be notified that by clicking on the link s/he will be leaving the Medicare information.
- Include a date/stamp on the bottom of each Web page with the date the page was last updated.
- Clearly label any links. When there is a link to a previously approved marketing material (e.g., SB, formulary, pharmacy/provider directory,) the plan must post the actual material, rather than duplicating the material's content on the website. These materials must also retain their original Material ID.
- Post all required translated materials that meet the 5% alternative language threshold.

100.2 - Required Content

All plan sponsor website content must be current and include:

- Information on beneficiaries' and plan's rights and responsibilities upon disenrollment.
- Service area listing.

- A list of premiums and cost-sharing (e.g., co-payments, co-insurance and deductibles) including any conditions and limitations.
- A list of any Out-of-Network Coverage rules.
- Instructions on how to appoint a representative and link to the CMS Appointment of Representative Form (CMS Form-1696).
- A description of and information on how to file, a grievance, a coverage determination and/or organization determination, and an appeal. This information must include:
 - Procedure for filing a coverage determination
 - Procedures for filing an organization determination
 - Phone number(s) for receiving oral requests.
 - Mailing address for written requests.
 - Fax number for written requests.
 - Links, if applicable to any forms created by the plan for appeals and grievances.
 - Information on how to obtain an aggregate number of grievances, appeals, and exceptions filed with the plan sponsor.
 - Contact numbers that enrollees and/or physicians can use for process or status questions.
- A direct link to the Medicare.gov website where a beneficiary can enter a complaint in lieu of calling 1-800-Medicare.

Part D sponsor website content must include:

- A direct link to CMS' Best Available Evidence policy on the CMS website.
- Direct links to the Request for Medicare Prescription Drug Determination Request Form(s) for enrollees and Providers found on CMS' Part D appeals webpage.
- Quality assurance policies and procedures, including Medication Therapy Management (MTM) information, and drug and/or utilization management information.

- Information about MTM programs including:
 - Plan sponsors' eligibility criteria and conditions for which MTM programs are available,
 - High level summary of services offered as part of the MTM program,
 - A statement clarifying that these programs are not considered a benefit,
 - A statement informing beneficiaries to contact the plan sponsor's customer service for additional information.

PFFS Plan websites must include:

- A link to Plan Sponsor's Terms and Conditions of Payment

MSA Plan websites must include the following statements:

- "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."
- "Tax publications are available on the IRS website at <http://www.irs.gov> or from 1-800-TAX-FORM (1-800-829-3676)."

100.2.1 – Required Documents for All Plan Sponsors

All plan sponsors must post the following materials:

- Summary of Benefits
- Enrollment Instructions and Forms
- Multi-language Insert
- Evidence of Coverage (most current version)
- Provider and/or Pharmacy Directory as applicable

- Privacy Notice (privacy notices are subject to enforcement by the Office for Civil Rights)
- CMS Plan Ratings document (star rating)
- Any form developed to be used by physicians when providing a supporting statement for an exceptions request
- 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.

100.2.2 – Required Documents for Part D Sponsors

Part D Plan sponsors must post the following materials:

- LIS Premium Summary Chart
- Prescription Drug Transition Policy
- Current Formulary (updated at least monthly if changes are made to the formulary)

100.3 - Online Enrollment

Except as described below, all plan sponsors must accept enrollment in a plan through the Online Enrollment Center (OEC).

- Medicare Savings Account (MSA) plans, and 800 series employer group waiver plans cannot accept enrollment through the OEC.
- SNPs and Religious Fraternal Benefit plans may, but are not required to, accept enrollment through the OEC.
- Section 1876 cost plans may but are not required to accept enrollment through the OEC.

Plan sponsors may develop and offer enrollment requests into a plan via its secure internet web site. (See Chapter 2 of the Medicare Managed Care Manual, Chapter 17d of the Medicare Managed Care Manual, and Chapter 3 of the Prescription Drug Manual for specific on-line enrollment website requirements).

Third party entities (on behalf of the plan sponsor) may make on-line enrollment available to potential enrollees via the plan sponsor's website or the OEC ONLY.

Enrollment via an agent/broker website is not permitted.

100.4 – Online Provider Directory Requirements

MA, MA-PD, and section 1876 cost plans must post a printable provider directory applicable for all products defined by service areas or general geographic area. This may be accomplished by:

- Posting a searchable “master” provider directory that represents the complete network for the plan sponsor.
- Posting individual provider directories by product and/or service area (e.g., mirroring those that will be printed for the plan sponsor’s membership).
- Using a search engine. If a plan sponsor uses a search engine on its website, it must include all the requirements in the model Directory.

100.5 – Online Formulary and Utilization Management (UM) Requirements

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

Part D plan sponsors may use an on-line formulary search tool, but such tools cannot be used as a substitute for downloadable documents (e.g., PDFs). PDF files must allow for printing, content copying for accessibility, page extraction, and document assembly.

Plan formularies must display all information contained within the HPMS formulary files. Plans will be allowed to make minor modifications to address issues such as abbreviations and/or grammatical truncation.

The information in the electronic formulary and/or UM documents must:

- Be available at the start of each new contract year enrollment period.
- Be updated at least once per month and must be accessible by a drug name search.
- Indicate when the documents/search tool was last updated by including the phrase, “Updated MM/YYYY” or “No changes made since MM/YYYY”.
- Define a formulary (either in a link or through an introductory screen).
- Provide an explanation of how to use the search tool.

- Include the following statement: “<Part D Plan Name> covers both brand name drugs and generic drugs. Generic drugs have the same active-ingredient formula as a brand name drug. Generic drugs usually cost less than brand name drugs and are rated by the Food and Drug Administration (FDA) to be as safe and effective as brand name drugs.”
- Include a statement that the formulary may change during the year.
- Provide search results that indicate whether a drug is covered, its tier placement, and any applicable utilization management requirements. If quantity limit restrictions apply, the quantity limit amount and days’ supply must be displayed. If prior authorization or step therapy restrictions are applicable, then the criteria must also be included.
- For drugs with a Part B versus D administrative prior authorization requirement, the following statement must be included: “This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination.”
- Provide an explanation of how to obtain an exception to the Part D plan’s formulary, utilization management tools or tiered cost sharing. This information or a link to this information must be included in both an introductory screen and when search results indicate a drug is not covered.
- Have an indicator to identify mail-order availability, excluded drugs, free first fill drugs, limited access drugs, drugs covered in the coverage gap, and drugs covered under the medical benefit (for home infusion drugs only).

Part D plan sponsors may include formulary and non-formulary alternatives; however, the formulary alternatives must be clearly marked as formulary drugs without the need for further navigation. If not all formulary alternatives will be listed, the plan must include the following disclaimer: “This is not a complete list of all formulary alternatives covered by the Part D plan for the drug you have selected.”

When applicable, plans must provide the notice associated with removing or changing a Part D drug, adding prior authorization, quantity limits, step therapy, changing the cost sharing status, or any other restrictions on a drug. This information must be maintained on the website until the next annual mailing of the updated formulary.

The notice must contain the following:

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

110 - Reserved

120 - Marketing and Sales Oversight and Responsibilities

120.1 - Compliance with State Licensure and Appointment Laws

42 CFR 422.2272(c), 423.2272 (c)

In order to sell Medicare products, plan sponsors must comply with applicable State licensure and/or appointment laws.

120.2 - Plan Reporting of Terminated Agents

42 CFR 422.2272(d), 423.2272(c), 422.2272 (d), 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.

When plan sponsors discover incidents of unlicensed agents or brokers submitting applications, they must terminate the agent/broker and report them 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 or brokers and advise those beneficiaries of the agents' and brokers' status. Beneficiaries may request to make a plan change.

120.3 - Agent/Broker Training and Testing

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

Plan sponsors must ensure that all brokers and agents selling Medicare products (including employed agents) are trained and tested annually on Medicare rules and regulations and on details specific to the plan products that they sell.

Specifications for training/testing criteria and documentation requirements will be provided annually by CMS. Plan sponsors must ensure that their training and testing programs are designed and implemented in a way that maintains the integrity of the training and testing, and must have the ability to provide this information to CMS upon request.

120.4 - Agent/Broker Compensation

42 CFR 422.2274(a), 423.2274(a)

CMS has established limits on agent and broker compensation in order to ensure that compensation does not create incentives for agents and brokers to assist beneficiaries with plan selection using criteria other than the beneficiaries' health care needs and preferences. These limits apply to MA organizations, Part D sponsors, and section 1876 cost plans that market through independent brokers or agents. These compensation rules are designed to eliminate inappropriate moves of beneficiaries from one plan to another. These compensation rules do not apply to employed agents or employer group plans.

120.4.1 - Definition of Compensation

42 CFR 422.2274(a), 423.2274(a)

Compensation includes pecuniary or non-pecuniary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes, awards, and finder's fees.

Compensation DOES NOT include:

- The payment of fees to comply with State appointment laws
- Training
- Certification

- Testing costs
- Reimbursement for mileage to, and from, appointments with beneficiaries
- Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials

120.4.2 - Compensation Types

42 CFR 422.2274(a)(1) and (3), 423.2274(a)(1) and (3)

The regulations provide for two types of compensation -- initial compensation and renewal compensation.

Initial compensation is offered for the beneficiary's initial year of enrollment in a plan. Renewal compensation is equal to fifty (50) percent of the initial compensation amount and is paid in the five (5) years following a beneficiary's initial year of enrollment in a plan. It is also paid when a beneficiary enrolls in a different plan but one that is a "like plan type" following the initial year of enrollment.

NOTE: Renewal compensation will apply whether or not the new enrollment is in a plan offered by the same or a new (receiving) organization, (e.g., the member moves to a different plan within the same parent organization).

A "like plan type" enrollment includes:

- A PDP to another PDP
- An MA or MA-PD to another MA or MA-PD
- A section 1876 cost plan to another section 1876 cost plan

An "unlike plan type" enrollment includes:

- An MA or MA-PD plan to a PDP or section 1876 cost plan
- A PDP to a section 1876 cost plan or an MA (or MA-PD) plan
- A section 1876 cost plan to an MA (or MA-PD) plan or PDP

NOTE: For dual enrollments, (e.g., enrollment in an MA-only plan and a stand-alone PDP), the compensation rules apply independently to each plan. However, when dual enrollments are replaced by an

enrollment in a single plan, compensation is paid based on the MA movement, (e.g., movement from an MA-only plan and PDP to an MA-PD plan would be compensated at the renewal compensation amount for the MA to MA-PD “like plan type” move).

120.4.3 - Compensation Cycle (6-Year Cycle)

42 CFR 422.2274(a), 423.2274(a)

Plan sponsors are required to pay independent agents/brokers on a 6-year compensation cycle. The first year is the initial year followed by 5 renewal years. If during a 6-year cycle, a plan member moves to a plan of a different plan type, the agent or broker may receive an initial compensation and the six (6)-year cycle starts over again. Once the compensation cycle expires, it does not restart until the beneficiary enrolls into another plan. Plan sponsors may continue to pay agents or brokers renewal compensation beyond the six (6)-year cycle at the plan’s discretion, as described in § 120.5.4. The monthly MARx agent/broker compensation report that is generated when an enrollment occurs will provide plan sponsors with the information necessary to determine whether they should make an initial or renewal payment.

120.4.4 - Developing and Implementing a Compensation Strategy

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’s enrollment is effective on September 1, then the initial year for that beneficiary ends on December 31, 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), have not been annually trained and tested per the plan's policies and procedures with a passing score of at least eighty-five (85) percent, or have been terminated for cause by the plan.
- 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.
- Plan sponsors cannot pay agent/brokers for the entire 6-year compensation cycle upfront, but may pay them annually, quarterly, monthly, or more frequently.
- Referral/finder's fees are part of total compensation. They are 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 stand-alone 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.

120.4.5 - Compensation Calculation

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.

120.4.6 - Recovering Compensation Payments (Charge-backs)

42 CFR 422.2274, 423.2274

Plans are required to recover compensation payments from agents under two circumstances: 1) when a beneficiary disenrolls from a plan within the first three months of enrollment (rapid disenrollment) and 2) any other time a beneficiary is not enrolled in a plan.

NOTE: When a member enrolls in a plan effective October 1, November 1, or December 1, and subsequently changes plans effective January 1 of the following year, this is not considered a rapid disenrollment. Therefore, plan sponsors cannot recover (charge-back) agent compensation payments. If, however, a beneficiary enrolls in October and disenrolls in December, then the plan sponsor should charge back because of a rapid disenrollment.

Plan sponsors should pay only for the actual months the beneficiary is enrolled in the plan. Plan sponsors should not recover funds when a beneficiary disenrolls within the first three months under the circumstances described below:

- Disenrollment from Part D due to:
- Other creditable coverage
- Institutionalization
- Under the following exceptional circumstances:
 - Gains/drops employer/union sponsored coverage
 - Because of a CMS sanction against the plan

- Because of plan terminations
- Because of a non-renewing section 1876 cost plan
- During the Medigap trial period
- In order to coordinate with Part D enrollment periods
- In order to coordinate with an SPAP
- Due to following changes in status:
 - Becoming dually eligible for both Medicare and Medicaid
 - Qualifying for another plan based on special needs
 - Becoming LIS eligible
 - Qualifying for another plan based on a chronic condition
 - Moves into or out of institution
- Due to an auto- or facilitated enrollment
- Involuntarily disenrollment for one of the following reasons:
 - Death
 - Moves out of the service area
 - Non-payment of premium
 - Loss of entitlement
 - Retroactive notice of Medicare entitlement
 - Contract violation
 - Plan non-renewal or termination
- When moving to a plan with a 5-star rating

120.4.7 - Adjustments to Compensation Schedules

42 CFR 422.2274, 423.2274

Plan sponsors must notify CMS annually whether they intend to use independent agents/brokers for the upcoming plan year and the amounts they will pay them.

Plan sponsors must pay independent agents/brokers an amount that is at or below the adjusted fair market value cut-off amounts (released each spring by CMS).

120.5 - Third Party Marketing Entities

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, (e.g., 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 - Additional Marketing Fees

42 CFR 422.2274(a), 423.2274(a)

A plan sponsor may not charge a beneficiary or allow its marketing representatives to charge a beneficiary a marketing fee. All costs associated with the marketing of a plan are the responsibility of the plan sponsor.

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

42 CFR 422.2274(c), 423.2274(c)

CMS clarifies that the following activities do not require the use of a State-licensed marketing representative. 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

130 - Employer/Union Group Health Plans

1857(i), 1860D-22(b), 42 CFR 422.2276, 423.2276

As provided in § 10.1 of Chapter 9 of the Medicare Managed Care Manual and § 10.1 of Chapter 12 of the Prescription Drug Benefit Manual, CMS has authority under sections 1857(i) and 1860D-22(b) of the Social Security Act to waive or modify requirements that hinder the design of, the offering of, or the enrollment in employment-based Medicare plans offered by employers and unions to their members. Waivers and modifications may be granted to plan sponsors offering “individual” PDPs or MA plans, or plan sponsors offering customized employer group PDPs or MA plans offered exclusively to employer/union group health plan sponsors (known as employer/union-only group waiver plans, or EGWPs). CMS has issued various employer group waivers and/or modifications to the Medicare Part C and Part D rules for marketing and disclosure/dissemination of information to Medicare beneficiaries. For specific guidance regarding these waivers or modifications of marketing and disclosure/dissemination of information requirements for employer/union-sponsored group health plans, please refer to § 20.3 of Chapter 9 of the Medicare Managed Care Manual, and § 20.3 of Chapter 12 of the Prescription Drug Benefit Manual.

Plan sponsors offering employer group health plans are no longer required to submit informational copies of their dissemination materials to CMS at the time of use. However, as a condition of CMS providing these particular waivers or modifications, CMS reserves the right to request and review these materials in the event of beneficiary complaints or for any other reason it determines to ensure the information accurately and adequately informs Medicare beneficiaries about their rights and obligations under the plan. For more information about these requirements, refer to § 20.3.2.1.1 of Chapter 9 of the Medicare Managed Care Manual, and § 20.3.2.1.1 of Chapter 12 of the Prescription Drug Benefit Manual.

Table 130-1. Marketing Provisions – Employer/Union Group Plans

Marketing Provisions that apply to Employer/Union Group Plans

These requirements are applicable for the transaction between the agent/broker selling the plan to the employer/union. All activities conducted by the employer/union or its designees to sign up individual employees to the plan(s) selected by the employer/union are excluded from these provisions.

Provision	Yes	No
Nominal Gifts	X	
Unsolicited Contacts		X
Cross-selling		X
Scope of Appointments		X
Sales/Marketing in Health Care Settings	X	
Sales/Marketing at Educational Events	X	
Co-branding	X	
Provision of Meals		X
Appointment of Agents/Brokers	X	
State Licensed	X	
Reporting of Terminated Agents/Brokers	X	
Agent/Broker Compensation		X
Agent/Broker Training and Testing – Agents must be thoroughly familiar with the products they are selling; including the plan specific details and the Medicare rules that apply to the specific products. The organization/sponsor is responsible for ensuring that the agents selling for them have sufficient knowledge.	X (training)	X (testing)

140 - Medicare Medical Savings Account (MSA) Plans

42 CFR 422.2264, 423.2264

MSAs are required to abide by all applicable guidance set forth in this chapter.

Additionally, MSA plans may not:

- Imply the plan functions as a supplement to Medicare.
- Use the term “network” to describe a list of contracted preferred providers.

See § 100 for additional MSA requirements related to websites.

150 - Use of Medicare Mark For Part D Plans

Section 1140 of the Social Security Act

All MA-PD plans, PDPs, section 1876 cost plans 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 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

Section 1140 of the Social Security Act

All Part D plans 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. Part D plans may use the mark on marketing materials consistent with this chapter.

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

Section 1140 of the Social Security Act

All Part D plans may use the Medicare Prescription Drug Benefit Program Mark on items they distribute, provided the item(s) follow(s) guidelines for nominal gifts, as provided in Appendix 1 and § 70.3. Items with the Medicare Prescription Drug Benefit Program Mark cannot be sold for profit.

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

Section 1140 of the Social Security Act

The process to grant authorized users access to the Medicare Prescription Drug Benefit Program Mark for use on Part D marketing materials is described below.

1. CMS counter-signs the plan sponsor's contract.
2. CMS sends a Medicare Prescription Drug Benefit Program Mark licensing agreement to plan sponsor.
3. Plan sponsor submits a signed licensing agreement to CMS.
4. CMS sends the Medicare Mark URL to the plan sponsor.

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.

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; and 2) approval will be granted only for those items for which use of the mark was requested in the request letter and for which written approval was granted.

150.4 - Restrictions on Use of Medicare Prescription Drug Benefit Program Mark

Section 1140 of the Social Security Act

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

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

150.5 - Prohibition on Misuse of the Medicare Prescription Drug Benefit Program Mark

Section 1140 of the Social Security Act and 42 U.S.C. §1320b-10

42 U.S.C. §1320b-10 prohibits the misuse of the Medicare name and marks. In general, it authorizes the Inspector General of the Department of Health and Human Services (DHHS) to impose penalties on any person who misuses the term Medicare or other names associated with DHHS in a manner which the person knows or should know gives the false impression that it is approved, endorsed, or authorized by DHHS. Offenders are subject to fines of up to \$5,000 per violation or in the case of a broadcast or telecast violation, \$25,000.

150.6 - Mark Guidelines

Section 1140 of the Social Security Act

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



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

150.6.1 - Mark Guidelines - Negative Program Mark

Section 1140 of the Social Security Act

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



150.6.2 - Mark Guidelines - Approved Colors

Section 1140 of the Social Security Act

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



The 1-color version in grayscale is acceptable. The mark elements are one-hundred (100) percent black except for the word "Medicare" which is fifty-five (55) percent black.



The 1-color version in one-hundred (100) percent black also is acceptable.



150.6.3 - Mark Guidelines on Languages

Section 1140 of the Social Security Act

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



150.6.4 - Mark Guidelines on Size

Section 1140 of the Social Security Act

To maintain clear legibility of the Program Mark, never reproduce it at a size less than one (1) inch wide. The entire mark must be legible.



150.6.5 - Mark Guidelines on Clear Space Allocation

Section 1140 of the Social Security Act

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



150.6.6 - Mark Guidelines on Bleed Edge Indicator

Section 1140 of the Social Security Act

The Program Mark may not bleed off any edge of the item. The mark should sit at least one-eighth (1/8) inch inside any edges of the item.

150.6.7 - Mark Guidelines on Incorrect Use

Section 1140 of the Social Security Act

Following are rules for preventing incorrect use of the Medicare Prescription Drug Benefit Program Mark:


- Do not alter the position of the mark elements.
- Do not alter the aspect ratio of the certification mark. Do not stretch or distort the mark.
- Always use the mark as provided.

- Do not rotate the mark or any of its elements.
- Do not alter or change the typeface of the mark.
- Do not alter the color of any of the mark elements.
- Do not position the mark near other items or images. Maintain the clear space allocation.
- Do not position the mark to bleed off any edge. Maintain one-eighth (1/8) inch safety from any edge.
- Do not use any of the mark elements to create a new mark or graphic.
- Do not use the mark on background colors, images or other artwork that interfere with the legibility of the mark.

150.7 - Part D Standard Pharmacy ID Card Design

Section 1140 of the Social Security Act

Usage of the Medicare Prescription Drug Benefit Program Mark on any item must be consistent with § 60.2 of this chapter.

Part D Plan Sponsor Name/Logo		<div style="border: 1px solid black; padding: 5px; text-align: center;"> sponsor logo place- holder </div>
RxBin	999999	
RxPCN	ABC1234567	
RxGrp	ABC123456789	
Issuer	(80840)	
ID	12345678901	
Name	JOHN Q PUBLIC	CMS - S5555 XXXX

160 - Allowable Use of Medicare Beneficiary Information Obtained from CMS

All MA, Part D, PACE, and section 1876 cost plans sign a data use attestation under which they agree that they will restrict the use of Medicare data to

those purposes directly related to the administration of the Medicare managed care and/or outpatient prescription drug benefits for which they have contracted with CMS to administer. Plan sponsors also agree not to use that information to develop, market, or operate lines of business unrelated to their Medicare plan operations.

For purposes of these Data Use Attestations, CMS-provided data includes information provided by beneficiaries in the course of their enrollment in a Medicare plan as well as data obtained solely as a result of access to CMS systems granted to the contracting organization or sponsor because it is a Part C, Part D, PACE or section 1876 cost plan contractor. Except in cases in which the enrollee gave information as part of a commercial relationship prior to enrollment in the Medicare plan, the contracting organization or sponsor was only given the information on the application as a result of the contract with CMS.

While plan sponsors with a previous commercial relationship with Medicare beneficiaries (and employers offering Medicare plans) may have obtained their personal data through that relationship, and therefore are not obligated to follow the guidelines set forth in the Data Use Agreement, we encourage plan sponsors to follow these data use guidelines as a good business practice for protecting beneficiaries from potentially unwelcome marketing and other communications. Examples of what is considered a previous commercial relationship include membership in such products as:

- Long-term care insurance
- Life-insurance policies
- Non-Medicare employer or retiree plans
- Medigap policies

While it is important to protect Medicare beneficiaries from potentially unwelcome marketing and other communications, we also recognize plan sponsors' interest in contacting their enrollees on issues unrelated to the specific plan benefit that they contract with CMS to provide. This section contains additional guidance for plan sponsors on the distribution of other types of non-plan related information.

160.1 - When Prior Authorization From the Beneficiary Is Not Required

Plan sponsor marketing materials describing health-related lines of business to current members do not require prior authorization (See 40.11 for

additional information). Examples of health-related information that do not require prior authorization include:

- Long-term care insurance
- Separate dental or vision policies
- Health-related value-added items and services (VAIS)
- Information about current plan coverage or other Medicare products offered by the plan sponsor
- Plan and health information in monthly newsletters
- Information on disease management programs
- Mailings describing benefits changes
- Information on Medicaid and other community or social services program

160.2 - When Prior Authorization From the Beneficiary Is Required

Plan sponsors must obtain authorization from an enrollee prior to using or disclosing the enrollee's protected health information for marketing purposes. For exceptions, see Appendix 2, Multiple Lines of Business - HIPAA Privacy Rule. Examples of non-health related issues plans may communicate after receiving prior authorization ("opt-in") of current enrollees include:

- Accident-only policies
- Life insurance policies
- Annuities
- Volunteer or community activities
- Pending State or Federal legislation
- Joining grassroots advocacy organizations and information about such advocacy

160.3 - Obtaining Prior Authorization

Following are examples of how the prior authorization required under §160.2 may be obtained. With any of these examples, plan sponsors must receive

the member's "opt-in" authorization prior to sending any non-plan or non-health related information, and plan sponsors should keep evidence of authorization for audit purposes.

- Plan sponsors may send, at their own expense, written requests to enrollees to obtain the beneficiary's authorization for the organization or sponsor to contact him/her for purposes unrelated to plan benefits administration or CMS contract execution. The beneficiary must sign and return the request before the plan can send non-plan related materials or information. This authorization may also be obtained by directing a beneficiary to a website to provide the requisite consent. Note that if the plan uses a website for the "opt-in" process, 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 provided in § 100.1. Once a beneficiary "opts-in," the plan sponsors must be clear that the beneficiary will receive additional information that may be non-plan or non-health related.
- Beneficiaries can complete a prior authorization in person at marketing events, health fairs, or other public venues.
- Beneficiaries can complete the prior authorization over the telephone, provided the authorization is recorded. The call must be a beneficiary-initiated inbound telephone call and scripts for such calls must comply with all guidance in § 80.
- Beneficiaries can complete the prior authorization via an email to the plan, provided that the authorization includes an electronic signature.

Regardless of the method by which the prior authorization is obtained, (e.g., written, telephonic, on a website), the following rules apply:

- The request must include one or more types of information for which authorization is being sought. If authorization is being sought for more than one type of information, a check box (or verbal agreement, if a telephonic authorization) needs to be assigned to each type of information. Furthermore, the type of information can only be described in general terms. For example, "Check the boxes of the types of information you would like to receive: life insurance, long-term care insurance, pending State and Federal legislation, grass-roots advocacy."
- The request for authorization should not include any non-plan or non-health related content, nor should it be included in the same mailing

as information on non-health related issues, unless the plan sponsor has previously received prior authorization to send that particular non-health related information to that member. For example, a request for authorization to send information about life insurance should not include a statement like "Make sure your spouse's future is secure, with a life insurance policy from us," and/or should not be sent with documents that include details about the life insurance policy.

- The request for authorization can be included in the same mailing as plan-related or health-related mailings to members, as provided in the MMG. The request for authorization may not be included on the enrollment form (whether in hard copy or in electronic forms available via the plan's website) or made during the processing of a telephonic enrollment.
- The request for authorization should not be confusing or misleading to members by purporting to have current plan benefit information or by suggesting that the content includes official information from the Medicare program.
- These requests for authorization are not subject to review by CMS, and should not be uploaded into HPMS. However, per § 20, plan sponsors are still responsible for ensuring that all materials intended for Medicare beneficiaries meet the requirements of this chapter.
- CMS is adopting the same requirements for these authorizations as required by the HIPAA Privacy Rule. Additional details on what is required for an acceptable attestation can be found at 45 CFR 164.508.

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

Non-plan and non-health related content can be provided to members once prior authorization is received.

- Non-health related content cannot be delivered with plan-related materials; including in mailings, on websites, or during outbound telephone calls related to current plan information.
- Health-related content can be included with plan-related materials. In addition, these materials should include the disclaimer, "Medicare has neither reviewed, nor endorses, this information."

Appendix 1 - Definitions

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 the MMG only.

Ad hoc Enrollee Communication Materials

Ad hoc enrollee communication materials are informational materials that are targeted to current enrollees, are customized or limited to a subset of enrollees, 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
- Customer service correspondence pertaining to unique questions or issues that affect an individual or small subset of the plan's enrollment

Note, model enrollment/disenrollment materials are not considered ad hoc enrollee communications.

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.

Alternate Formats

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

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, (e.g., 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.

Direct mail

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.

Educational Event

Educational events are designed to inform Medicare beneficiaries about Medicare Advantage, Prescription Drug or other Medicare programs and do not include marketing, (i.e., the event sponsor does not steer, or attempt to steer, potential enrollees toward a specific plan or limited number of plans).

Enrollment Materials

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

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.

Marketing

Marketing is the act of 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.

Marketing Materials

Marketing materials are any materials targeted to Medicare beneficiaries that:

1. Promote the plan sponsor, or any MA plan, MA-PD plan, section 1876 cost plan, or PDP offered by the plan sponsor.
2. 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.
3. Explain the benefits of enrollment in an MA plan, MA-PD plan, section 1876 cost plan, or PDP or rules that apply to enrollees.
4. 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.

Model Document

Model documents are materials for which CMS has provided model language which, when used without modification, qualifies for a 10-day review or for submission through the File & Use process.

Multi Contract Entities (MCE)

MCE is a designation available for plan sponsors that have multiple MA/PDP contracts with CMS. Being designated as an MCE allows a plan sponsor to submit template materials to CMS that are representative of all or a selection of the plan sponsor's contracts.

Nominal Value

Nominal value is defined as an individual item/service worth \$15 or less (based on the retail value of the item).

Outdoor Advertising (ODA)

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

Post-Enrollment Marketing Materials

Post-enrollment marketing material is a subset of marketing materials used by a plan sponsor to convey benefits or operational information to current enrollees.

Pre-Enrollment Marketing Materials

Pre-enrollment marketing material is a subset of marketing materials used prior to enrollment. Pre-enrollment materials may contain plan rules and/or benefit information.

Promotional Activities

Promotional activities are activities performed by a plan sponsor, or by an individual or organization on a plan sponsor's behalf, to inform current and potential enrollees of the products available.

Standardized Language

Standardized language is language developed by CMS or another Federal agency that is mandatory for use by the plan sponsor and cannot be modified except as noted by CMS (e.g., ANOC/EOC, SB, Plan Ratings).

Template Materials

Template materials are any marketing materials that include placeholders for variable data to be populated at a later time.

Third Party Marketing Organization (TMO)

Third-party marketing organizations are entities 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).

Appendix 2 – Related Laws and Regulations

(Not an exhaustive list)

Use of the Medicare Name

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 & Medicaid Services,” “Department of Health and Human Services,” or “Health & 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.

Privacy and Confidentiality

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. 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 § 20 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/>.

Multiple Lines of Business - HIPAA Privacy Rule

45 CFR 160

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

to make communications to enrollees about other lines of business provided by the covered entity.

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

Telephonic Contact

Federal Trade Commission's Requirements for Sellers and Telemarketers apply including:

- Federal Communications Commission rules and applicable State law
- National-Do-Not-Call Registry
- "Do not call again" requests, and
- Federal and State calling hours

Use of Federal Funds

(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 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."

Section 508 of the Rehabilitation Act

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

All plan sponsors are required to have an Internet website that is compliant with web-based technology and information standards for people with disabilities as specified in section 508 of the Rehabilitation Act. For additional information, please go to the following website address:
<http://www.section508.gov>.

NOTE: These Federal requirements are extended to all plan sponsors through the requirements for non-discrimination under Federal grants and programs (29 USC §794).

Mailing Standards

Plan sponsors must comply with the mailing standards of the United States Postal Service contained in the Domestic Mail Manual.

Appendix 3 - Model File & Use Certification Form

[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, Regulations, and sub-regulatory guidance. 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/1876 cost plan>.

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.

Appendix 4 – Multi-Language Insert

Multi-language Interpreter Services

English: We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1-xxx-xxx-xxxx]. Someone who speaks English/Language can help you. This is a free service.

Spanish: Tenemos servicios de intérprete sin costo alguno para responder cualquier pregunta que pueda tener sobre nuestro plan de salud o medicamentos. Para hablar con un intérprete, por favor llame al [1-xxx-xxx-xxxx]. Alguien que hable español le podrá ayudar. Este es un servicio gratuito.

Chinese Mandarin: 我们提供免费的翻译服务，帮助您解答关于健康或药物保险的任何疑问。如果您需要此翻译服务，请致电 1-xxx-xxx-xxxx。我们的中文工作人员很乐意帮助您。这是一项免费服务。

Chinese Cantonese: 您對我們的健康或藥物保險可能存有疑問，為此我們提供免費的翻譯服務。如需翻譯服務，請致電 1-xxx-xxx-xxxx。我們講中文的人員將樂意為您提供幫助。這是一項免費服務。

Tagalog: Mayroon kaming libreng serbisyo sa pagsasaling-wika upang masagot ang anumang mga katanungan ninyo hinggil sa aming planong pangkalusugan o panggagamot. Upang makakuha ng tagasaling-wika, tawagan lamang kami sa [1-xxx-xxx-xxxx]. Maaari kayong tulungan ng isang nakakapagsalita ng Tagalog. Ito ay libreng serbisyo.

French: Nous proposons des services gratuits d'interprétation pour répondre à toutes vos questions relatives à notre régime de santé ou d'assurance-médicaments. Pour accéder au service d'interprétation, il vous suffit de nous appeler au [1-xxx-xxx-xxxx]. Un interlocuteur parlant Français pourra vous aider. Ce service est gratuit.

Vietnamese: Chúng tôi có dịch vụ thông dịch miễn phí để trả lời các câu hỏi về chương sức khỏe và chương trình thuốc men. Nếu quý vị cần thông dịch viên xin gọi [1-xxx-xxx-xxxx] sẽ có nhân viên nói tiếng Việt giúp đỡ quý vị. Đây là dịch vụ miễn phí.

German: Unser kostenloser Dolmetscherservice beantwortet Ihren Fragen zu unserem Gesundheits- und Arzneimittelplan. Unsere Dolmetscher erreichen Sie unter [1-xxx-xxx-xxxx]. Man wird Ihnen dort auf Deutsch weiterhelfen. Dieser Service ist kostenlos.

Korean: 당사는 의료 보험 또는 약품 보험에 관한 질문에 대해 드리고자 무료 통역 서비스를 제공하고 있습니다. 통역 서비스를 이용하려면 전화 [1-xxx-xxx-xxxx]번으로 문의해 주십시오. 한국어를 하는 담당자가 도와 드릴 것입니다. 이 서비스는 무료로 운영됩니다.

Russian: Если у вас возникнут вопросы относительно страхового или медикаментного плана, вы можете воспользоваться нашими бесплатными услугами переводчиков. Чтобы воспользоваться услугами переводчика, позвоните нам по телефону [1-xxx-xxx-xxxx]. Вам окажет помощь сотрудник, который говорит по-русски. Данная услуга бесплатная.

Arabic:

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Italian: È disponibile un servizio di interpretariato gratuito per rispondere a eventuali domande sul nostro piano sanitario e farmaceutico. Per un interprete, contattare il numero [1-xxx-xxx-xxxx]. Un nostro incaricato che parla Italianovi fornirà l'assistenza necessaria. È un servizio gratuito.

Portugués: Dispomos de serviços de interpretação gratuitos para responder a qualquer questão que tenha acerca do nosso plano de saúde ou de medicação. Para obter um intérprete, contacte-nos através do número [1-xxx-xxx-xxxx]. Irá encontrar alguém que fale o idioma Português para o ajudar. Este serviço é gratuito.

French Creole: Nou genyen sèvis entèprèt gratis pou reponn tout kesyon ou ta genyen konsènan plan medikal oswa dwòg nou an. Pou jwenn yon entèprèt, jis rele nou nan [1-xxx-xxx-xxxx]. Yon moun ki pale Kreyòl kapab ede w. Sa a se yon sèvis ki gratis.

Polish: Umożliwiamy bezpłatne skorzystanie z usług tłumacza ustnego, który pomoże w uzyskaniu odpowiedzi na temat planu zdrowotnego lub dawkowania leków. Aby skorzystać z pomocy tłumacza znającego język

polski, należy zadzwonić pod numer [1-xxx-xxx-xxxx]. Ta usługa jest bezpłatna.

Hindi:

, 1-XXX-XXX-XXXX]

Japanese: 当社の健康 健康保険と薬品 処方薬プランに関するご質問にお答えするために、無料の通訳サービスがあります。通訳をご用命になるには、[1-xxx-xxx-xxxx]にお電話ください。日本語を話す人 者が支援いたします。これは無料のサービスです。

Appendix 5 – Pharmacy Technical Help/Coverage Determinations and Appeals Call Center Requirements

Pharmacy Technical Help Call Center Requirements

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; inquiries may pertain to operational areas such as claims processing, benefit coverage, claims submission, and claims payment. 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. 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, (e.g., 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 not to exceed two (2) minutes. The average hold time is defined as the time spent on hold by the caller following the interactive voice response (IVR) system, touch tone response system, or recorded greeting and before reaching a live person.
- Eighty (80) percent of incoming calls answered within thirty (30) seconds.
- Disconnect rate of all incoming calls not to exceed five (5) percent.

Coverage Determinations and Appeals Call Center Requirements

42 CFR 422.111(b)(8), 423.128(b)(7), (d)(1)(iv), 423.566(a)

All plan sponsors (except 1876 cost plan sponsors that do not offer Part D) must operate a toll-free call center with live customer service representatives available to respond to providers or enrollees for information related to coverage determinations (including exceptions and prior authorizations), appeals. Plan sponsors are required to provide immediate access to the coverage determination and redetermination processes via

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

Voicemail may be used outside of normal business hours provided the message:

- Indicates that the mailbox is secure.
- Lists the information that must be provided so the case can be worked, (e.g., provider identification, beneficiary identification, type of request (coverage determination or appeal), physician support for an exception request, and whether the member is making an expedited or standard request).
- For coverage determination calls (including exceptions requests), articulates and follows a process for resolution within twenty-four (24) hours of call for expedited requests and seventy-two (72) hours for standard requests.
- For appeals calls, information should articulate the process information needed and provide for a resolution within seventy-two (72) hours for expedited appeal requests and seven (7) calendar days for standard appeal requests.