

Medicare Marketing Guidelines

For Medicare Advantage Plans¹, 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) (also referred to as Plan), Medicare Prescription Drug Plan (PDP) (also referred to as Part D Sponsor), and except where otherwise specified 1876 cost **plans** (also referred to as Plan) 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 Health Care Pre-payment Plans. These requirements also apply to Medicare-Medicaid Plans (MMPs), except as modified or clarified in state-specific marketing guidance for each state's demonstration. State-specific guidance is considered an addendum to the MMG. State-specific marketing guidance for MMPs will be posted to <http://cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialModelstoSupportStatesEffortsinCareCoordination.html> as it is finalized.

The term "marketing" is referenced at Section 1851(h) and 1860 D-4 of the Social Security Act (the Act), as well as in CMS regulations. The scope of the definition extends beyond the public's general concept of advertising materials.

Pursuant to 42 CFR section 417.428, section 422.2260, and section 423.2260, **the following materials**, while not an exhaustive list, 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, enrollee handbooks and wallet card instructions to enrollees (**e.g., Evidence of Coverage (EOC)**)
- Communications to enrollees about contractual changes, and changes in providers, premiums, benefits, plan procedures, etc. (**e.g., Annual Notice of Change (ANOC), Provider/Pharmacy Directory**)

- 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's/Part D Sponsor's employees, independent agents or brokers, Third Party Marketing Organizations (TMO) (downstream contractors) 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/Part D Sponsor for marketing activities

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

- Plans/Part D 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
- Plans/Part D Sponsors are responsible for full disclosure when providing information about plan benefits, policies, and procedures
- Plans/Part D 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's/Part D Sponsor's Account Manager or designated Marketing Reviewer.

20 – Materials Not Subject To **Marketing** Review

42 CFR 422.2260, 422.2262, 423.2260, 423.2262

The following items are materials that are not subject to **marketing** review by CMS, should not be uploaded into HPMS, and do not require a material ID number. However, Plans/Part D Sponsors are still responsible for maintaining such materials so as to make them available, **through HPMS or other means**, upon CMS request.

- Privacy notices (which are subject to enforcement by the Office for Civil Rights)
- OMB-approved forms/documents, **except when otherwise specified by CMS**
- Press releases that do not include any plan-specific information (examples of plan-specific information include information about benefits, premiums, co-pays, deductible, benefits, how to enroll, networks)
- Certain enrollee newsletters unless sections are used to enroll, disenroll, and communicate with enrollees on product specific information (examples of product specific information include 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 (examples of general health promotion materials include 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 (examples of materials within this category include notice of check return for insufficient funds, letter stating Medicare ID number provided was incorrect, billing statements/invoices, sales, and premium payment coupon book)
- Documents to recruit or train sales/marketing representatives
- Medication Therapy Management (MTM) program materials (see Appendix 1)
- Ad hoc Enrollee Communications Materials (see definition in Appendix 1)
- Materials used at educational events for the education of beneficiaries and other interested parties (refer also to 70.8)
- Coordination of Benefits notifications (as provided in Chapter 14 of the Medicare Prescription Drug Benefit Manual)
- Health Risk Assessments
- Mail order pharmacy election forms

- Enrollee surveys
- Value-Added Items and Services (VAIS materials (refer to Chapter 4 of the Medicare Managed Care Manual))
- Communicating preventive services to enrollees
- Mid-year Change Enrollee Notifications (Refer to [60.8](#))
- **Informational Scripts**

30 - Plan/Part D Sponsor Responsibilities

30.1 - Limitations on Distribution of Marketing Materials **and Activities**

42 CFR 422.2262(a), 423.2262(a), 422.2260, 423.2260, 422.2268(e), 423.2268(e)

A Plan/Part D 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 Metropolitan Statistical Area that covers two regions), Plans/Part D Sponsors are required to clearly disclose their service area.

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 Plans/Part D 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.

NOTE: Marketing for an upcoming plan year may not occur prior to October 1. Plans/Part D Sponsors must cease current year marketing activities to existing beneficiaries once they begin marketing benefits for the new contract year. Prior year materials may be provided upon request and enrollment applications may be processed.

30.2 - Co-branding

42 CFR 422.2268(n), 423.2268(n)

Plans/Part D Sponsors must input any co-branding relationships, including any changes in or newly formed co-branding relationships, prior to marketing its new relationship, in the Health Plan Management System (HPMS). Plans/Part D

Sponsors should reference the HPMS user guide for instructions on entering co-branding information.

30.2.1 - Co-branding with Providers or Downstream Entities

42 CFR 422.2262(a), 422.2268(n), 423.2262(a), 423.2268(n)

Plans are prohibited from displaying the names and/or logos of co-branded providers on the Plan'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). **Part D sponsors are prohibited from displaying the names and/or logos of co-branded providers on the Part D Sponsor's member identification card.**

Plans/Part D Sponsors that choose to co-brand with providers must include on marketing materials (other than ID cards) the language in section [50.9](#). Neither the Plan/Part D 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/Part D 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 enrollee ID card.

30.2.2 – Plan's/Part D Sponsor's Relationships with State Pharmaceutical Assistance Programs (SPAP)

A Plan's/Part D 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 relationship.

30.3 – Plan/Part D Sponsor Responsibility for Subcontractor Activities and Submission of Materials for CMS Review

42 CFR 422.504(e)(2), 423.505, 422.2262(a), 423.2262(a)

Plans/Part D Sponsors are responsible for all marketing materials used by their subcontractors to market their plan(s). All marketing materials used by Plans/Part D Sponsors or their subcontractors must be submitted by the Plan/Part D Sponsor (or its designee) to CMS for review and approval (or acceptance).

Employer group health plans should refer to section [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/Part D Sponsor to CMS. Materials that include an agent's/broker's phone number should clearly indicate that calling the agent/broker number will direct an individual to a licensed insurance agent/broker.

NOTE: Exclusions from this requirement include:

- Business cards **that do not mention plan specific benefits**
- Materials that only indicate the products (e.g., HMO, PPO, or PDP) an agent sells

Please note that this guidance in no way precludes the application by the Plans/Part D Sponsors of more stringent rules or contractual obligations in order to further restrict agent or broker communication and activities.

30.4 - Anti-Discrimination

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

Plans/Part D 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. Plans/Part D Sponsors may not target beneficiaries from higher income areas or state or otherwise imply that they are available only to seniors rather than to all Medicare beneficiaries. Only Special Needs Plans (SNPs) and MMPs 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.

30.5 - Requirements Pertaining to Non-English Speaking Populations

42 CFR 422.111(h)(1), 423.128(d)(1)(iii), 422.2264(e), 423.2264(e)

All Plans'/Part D 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.

Plans/Part D Sponsors must make the marketing materials identified in sections [30.6](#), [30.7](#), [30.10](#), and the Part D Transition Letter(s) available in any language that is the primary language of at least five (5) percent of a Plan's/Part D

Sponsor's plan benefit package service area. **Final populated translations of all marketing materials must be uploaded into HPMS.**

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

CMS strongly encourages Plans/Part D Sponsors to translate ad-hoc communications upon request.

30.5.1 – Multi-Language Insert

42 CFR 422.111(h), 422.2262(c), 422.2264(a), 423.128(d) 423.2262(c), 423.2264(a)

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 30.5), all Plans/Part D Sponsors must include the CMS created Multi-Language Insert with the Summary of Benefits (SB), ANOC/EOC, and the enrollment form. Plans/Part D Sponsors have the option to incorporate the Multi-Language Insert as part of these materials or provide it as a separate document.

Please see Appendix [3](#). The Multi-Language Insert cannot be modified except to include additional languages and/or inserting the Plan/Part D Sponsor logo/name. If a Plan/Part D Sponsor chooses to include additional languages on the insert, they must do so by translating the statement referenced above.

NOTE: Dual SNPs (D-SNPs) that 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.

30.6 - Required Materials with an Enrollment Form

42 CFR 422.111, [422.2264](#), 423.128, [423.2264](#)

When a beneficiary is provided with enrollment instructions/form, s/he must also receive Star Ratings information (as specified in [30.10](#)), the SB, and the Multi-Language Insert (see section [30.5.1](#)).

NOTE: When a Plan/Part D Sponsor enrolls a beneficiary online, it must make these materials available electronically (e.g., via website links) to the potential enrollee prior to the completion and submission of the enrollment request.

30.7 - Required Materials for New and Renewing Enrollees at Time of Enrollment and Thereafter

42 CFR 422.111(c)(1), 423.128(c)(1), 422.2264(a), 423.2264(a)

- ANOC/EOC or EOC as applicable (required annually by Plan/Part D Sponsor, see section [60.7](#) for additional information)
- Low Income Subsidy (LIS) Rider (Part D Sponsors only, see the Prescription Drug Benefit Manual, Chapter 13, section 70.2 for additional information, including timeframes (<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html>))
- Comprehensive formulary or abridged formulary including information on how the beneficiary can obtain a **comprehensive** formulary (Part D sponsors only, see section [60.5](#) for additional information)
- Pharmacy directory (Part D Sponsors only, this is required at time of enrollment; see section [60.4.1](#) for additional information)
- Provider directory (For all plan types except PDPs, this is required at time of enrollment; see section [60.4.2](#) for additional information)
- Membership Identification Card (required at time of enrollment and as needed or required by Plan/Part D Sponsor post-enrollment; see section [60.2](#) for additional information)

These documents are expected to 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 is later. For exceptions to the 10-day requirement related to the LIS Rider, please see Prescription Drug Benefit Manual, Chapter 13 - Premium and Cost-Sharing Subsidies for Low-Income Individuals, 70.2 - Enrollee Notifications. Plans/Part D 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.

30.7.1 – Mailing Materials to Addresses with Multiple Enrollees

42 CFR 422.111, 423.128, 422.2264, 423.2264

Every enrollee must receive the materials noted in [30.7](#) at the time of enrollment. Plans/Part D Sponsors may combine the mailing of these materials to enrollees at the same address after receiving consent from all the enrollees. 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.

NOTE: Plans/Part D Sponsors may not mail one membership identification card to an address where multiple enrollees reside; all enrollees must receive individual membership identification cards.

30.8 - Hold Time Messages

42 CFR [422.2262](#), 422.2268(f), [423.2262](#) and 423.2268(f)

Hold time messages (messages played when an enrollee or prospective enrollee is on hold when calling the plan) that promote the plan or include benefit information must be submitted in HPMS for review as marketing materials. **In addition, Plans/Part D Sponsors are prohibited from using hold time messages to sell other products.**

30.9 – Enrollee Referral Programs

42 CFR 422.2268(a),(b), and (d), 423.2268(a),(b), and (d),

The following general guidelines apply to referral programs under which a Plan/Part D Sponsor solicits leads from enrollees for new enrollees. These include gifts that would be used to thank enrollees for devoting time to encourage enrollment.

- A Plan/Part D Sponsor can ask for referrals from enrollees, including names and mailing addresses, but cannot request phone numbers or email addresses
- Plans/Part D Sponsors may use enrollee provided referral names and mailing addresses to solicit potential new enrollees by conventional mail only
- Any solicitation for leads, including letters sent from Plans/Part D Sponsors to enrollees, cannot announce that a gift will be offered for a referral

- Gifts must be of nominal value (refer to section [70.1.1](#) - Nominal Gifts, [and 70.2 and 70.3](#) for additional guidance on limits for gifts provided to enrollees or prospective enrollees)

30.10 - Star Ratings Information from CMS

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

Plans/Part D Sponsors must provide Star Ratings information to beneficiaries through the standardized Star Ratings information document. The Star Ratings information document must be distributed with any enrollment form and/or the SB. [The Star Ratings information document must also be prominently posted on plan websites.](#)

To create this document, Plans/Part D Sponsors must download Star Ratings 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 Star Ratings Template.

Plans/Part D Sponsors have the option to add their plan logo to the document. No additional alterations may occur unless otherwise directed by CMS.

Star Ratings are generally issued in October of each year. Plans/Part D Sponsors will be required to use updated Star Ratings information within [21 calendar](#) days of the release of the updated information.

New Plans/Part D Sponsors that do not have any Star Ratings information are not required to provide Star Ratings information until the [next](#) contract year.

[However, small Plans/Part D Sponsors that do not have complete Star Ratings information due to insufficient sample sizes for certain measures must include the standardized Star Ratings information document with any enrollment form and/or the SB as described above.](#)

30.10.1 – Referencing Star Ratings in Marketing Materials

42 CFR [422.2262](#), [422.2264](#), 422.2268(e), [423.2262](#), [422.2264](#), 423.2268(e)

- Plans/Part D Sponsors may only reference a contract's individual measures in conjunction with its highest Rating (MAPD- overall rating, MA only- Part C summary rating, and PDP- Part D summary rating) in marketing materials. Plans/Part D Sponsors may not use their Star Rating in an [individual underlying](#) category or measure to imply higher overall or summary Star Ratings in their marketing materials. For example, a Plan/Part D Sponsor that received an overall rating of 2 stars, and a 5-star rating in the category of customer service may not promote itself as a "5-star plan."

- Plans/Part D 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
- Plans/Part D Sponsors must include the disclaimer noted in section [50.14](#) on materials that refer to Star Rating
- Plans/Part D Sponsors may direct beneficiaries to www.Medicare.gov for more information on Star Ratings
- Plans/Part D Sponsors may only market their Star Ratings for contracts in that geographic service area as specified in section [30.1](#)-Limitations on Distribution of Marketing Materials

NOTE: Plans/Part D Sponsors are responsible for translating Star Ratings information as specified in section 30.5. Translation of Star Ratings information will not be considered an alteration of the document.

30.10.2 –Plans with an Overall 5-Star Rating

42 CFR 422.2262, 422.2264, 422.2268(e), 423.2262, 422.2264, 423.2268(e)

Plans/Part D Sponsors with overall 5-star ratings may market their ability to enroll beneficiaries through the 5-star special enrollment period (SEP). However, they must refrain from doing so in a manner that specifically targets beneficiaries enrolled in poor performing plans, and they may not direct the beneficiary to request an SEP.

Plans/Part D 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. CMS' Regional Offices will provide the gold star icon to Plans/Part D Sponsors every Fall.

If a Plan/Part D Sponsor with an overall 5-star rating is **evaluated as having** a rating of less than 5 stars for the upcoming year, the Plan/Part D Sponsor must discontinue marketing for the purpose of accepting enrollments under the 5-star SEP by November 30 of the current year.

Plans/Part D Sponsors with one or more contracts with an overall 5-star rating should not create or disseminate materials in a way that implies that all of their contracts achieved this rating. Materials should list specific contracts with overall 5-star ratings.

30.10.3 –Low Performing Plans

42 CFR 422.2262, 422.2264, 422.2268(e), 423.2262, 422.2264, 423.2268(e)

- Plans/Part D Sponsors assigned a Low Performing Icon (LPI) by CMS may not attempt to discredit or refute their LPI status by only showcasing a higher overall Star Rating. If an MA-PD plan has been assigned an LPI, due to either low Part C and/or Part D ratings, the organization must clearly indicate its LPI status when referencing its Star Rating. For example, an MA-PD plan has a 3-star overall rating but has an LPI because of its low Part C ratings may advertise that its overall Star Rating is 3, but it must also include that it has a LPI for low Part C performance. In addition, the organization must state that its LPI status means that it received a 2.5-star or below summary rating in either Part C and/or Part D for the last three years. In cases where the organization received an LPI due to alternating low performance on Part C and Part D ratings, the most recent low rating must be noted.
- Plans/Part D Sponsors cannot encourage beneficiaries to enroll based on the argument that if they are dissatisfied with the plans, they can later request SEPs and change to higher-rated plans.
- If Plans/Part D Sponsors wish to respond to CMS-issued beneficiary notices, the proposed response must be approved by CMS prior to use. Prior CMS approval is required unless identical materials have been previously reviewed and approved by CMS. Outreach materials may focus on the efforts of the organization to improve its Star Ratings, but cannot:
 - dispute the validity or importance of CMS' Star Ratings,
 - dispute the validity of the plan's low rating, or
 - state or imply that the enrollee is responsible for the plan's poor rating and/or needs to take specific actions for the plan's future success.

40 - General Marketing Requirements

40.1 - Marketing Material Identification

42 CFR 422.2262(a)(1)(i) and (c), 423.2262(a)(1)(i) and (c), 422.2264, 423.2264

Plans/Part D Sponsors are required to place a unique marketing material identification number on all marketing materials (except as indicated below) to facilitate CMS review of and oversight of marketing materials.

The material ID is made up of two parts: (1) Plans'/Part D 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/Part D 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 Approved). Please note that Plans/Part D Sponsors should include approved statuses only after the material is approved and not when submitting the material for review.

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

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

NOTE: Refer to section [90.2.3](#) 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 using the method outlined above. When submitting these materials, Plans/Part D Sponsors must designate that they are non-English or alternate format versions in HPMS.

40.2 - Font Size Rule

42 CFR 422.2264(a), 423.2264(a)

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/Part D Sponsor publishes a notice to close enrollment in the *Public Notices* section of a newspaper, the Plan/Part D 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/Part D 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/Part D Sponsor codes the font for the Web page rather than how it actually appears on the user's screen.

40.3 - Reference to Studies or Statistical Data

42 CFR 422.2264(a)(4), 422.2268(e), 423.2264(a)(4), 423.2268(e)

Plans/Part D Sponsors may only compare their plan to another Plan/Part D Sponsor by referencing a study or statistical data as described below.

- Plans/Part D Sponsors must provide the study sample size, number of Plans/Part D Sponsors surveyed, publication date, and page number in the HPMS marketing material transmittal comments field when uploading the document that includes the reference
- Plans/Part D Sponsors must make it clear that the study or statistical data is not endorsed by CMS
- In the event that a Plan/Part D Sponsor uses a non-CMS award/survey in its marketing materials, the Plan/Part D sponsor must:
 - prior to citing the study/survey data, provide CMS with detailed information about the study/survey which resulted in the award in compliance with Section 40.3;
 - explicitly state that 1) the award was not given by Medicare; and 2) the plan's official CMS Star Rating can be found at www.Medicare.gov; and
 - give equal prominence (font size and/or screen time) to the Medicare Star Rating relative to other awards or surveys mentioned.

Plans/Part D Sponsors must provide the following information, either in the text or as a footnote, on marketing pieces (including but not limited to informational scripts) that mention a study:

- The source and date of the study
- Information about the Plan's/Part D 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 **422.2262**, 422.2264, **423.2262**, 423.2264, 422.2268(e), 423.2268(e)

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

Plans/Part D 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") **and/or qualified superlatives (e.g., "one of the best," "among the highest rank")** unless they are substantiated with supporting data provided to CMS as a part of the marketing review processes or they are used in logos/taglines. 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. **The superlatives used and the data provided must be in context and may not mislead consumers. For example, a Plan/Part D Sponsor that is the only plan in the area that received a 5-star rating in customer service, but received an overall rating of 3 stars, may not promote itself as the highest ranked plan in a service area where other plans have a higher overall rating.**
- **Other than the exceptions noted in section 40.3,** compare their Plan/Part D Sponsor to another Plan/Part D Sponsor by name **without** written concurrence from all Plans/Part D Sponsors being compared. This documentation must be included when the material is submitted in HPMS.

Plans/Part D Sponsors may:

- State that the Plan/Part D Sponsor is approved for participation in Medicare programs and/or it is contracted to administer Medicare benefits
- Use the term "Medicare-approved" to describe their benefits and services within their marketing materials

40.5 - Product Endorsements/Testimonials

42 CFR 422.2264, 423.2264, 422.2268, 423.2268

Product endorsements and testimonials will **be considered helpful to enable the beneficiary to make informed decisions and therefore** not be considered misleading if they adhere to the following:

- The speaker must identify the Plan's/Part D Sponsor's product by name
- **Medicare beneficiaries endorsing** a Plan/Part D Sponsor or promoting a specific product **must be current enrollees of that Plan/Part D Sponsor**
- If an 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 **or other** health care providers
- The endorsement or testimonial cannot use negative testimonials about other Plans/Part D Sponsors

NOTE: Re-publication of individual users' content or comment that promotes a Plan's/Part D Sponsor's product from social media sites is considered a product endorsement/testimonial and must adhere to the guidance in this section.

40.6 - Hours of Operation Requirements for Marketing Materials

42 CFR 422.111(h), 422.2262(c), 423.128(d), 423.2262(c)

A Plan's/Part D Sponsor's hours of operation should be listed on every material where a customer service number is provided, **excluding ID cards**, for current and prospective enrollees to call. Similarly, a Plan/Part D Sponsor must list the hours of operation for 1-800-MEDICARE on every material where 1-800-MEDICARE or Medicare TTY appears (i.e., 24 hours a day/7 days a week).

NOTE: The hours of operation need to only be listed once in conjunction with the customer service number and 1-800-MEDICARE; they do not need to be listed every time a customer service number is provided.

- The Plan/Part D Sponsor customer service number must be a toll-free number

- 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

Refer to section [80.1](#) for additional guidance for customer call centers.

40.7 - Use of TTY Numbers

Section 501 and Section 504 of the Rehabilitation Act

A TTY number must appear in conjunction with the Plan's/Part D Sponsor's customer service number in the same font size and style as the other phone numbers except as outlined below. Plans/Part D 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 3)
- Radio ads and radio sponsorships (e.g., sponsoring an hour of public radio)

In television ads, the TTY number may be a different font size/style than other phone numbers to limit possible confusion. Plans/Part D Sponsors may use various techniques to distinguish 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).

40.8 - Marketing of Multiple Lines of Business

42 CFR 422.2268(e), (f) and (h), 423.2268(e), (f) and (h)

Plans/Part D Sponsors cannot market non-health related products to prospective enrollees during an MA or Part D sales activity. **Plans/Part D Sponsors** may provide marketing materials describing other **health-related** lines of business when marketing covered plans, provided that such materials are in compliance with applicable State law governing the other lines of business **and Federal Medicare regulations**. When doing so, Plans/Part D Sponsors are encouraged to adhere to the **guidance** set forth in this section, as well as section [160](#).

40.8.1 - Multiple Lines of Business - General Information

42 CFR 422.2268(e-f), 423.2268(e-f)

Plan/Part D Sponsor marketing materials sent to current enrollees describing other health-related lines of business **are expected to** contain instructions that describe how individuals may opt out of receiving such communications. Plans/Part D Sponsors must ensure individuals (including non-enrollees) who ask to opt out of receiving future marketing communications are not sent such communications. In marketing multiple lines of business, Plans/Part D Sponsors must comply with the Health Insurance Portability and Accountability Act (HIPAA) rules (outlined generally in Appendix [2](#)) and the guidance in section [160](#) regarding use of beneficiary information.

Plans/Part D Sponsors that advertise multiple lines of business within the same marketing document must keep the organization's Medicare lines of business clearly and understandably distinct from the other products.

Plans/Part D 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. **Such activities are considered cross-selling and potentially misleading in violation of the rules.**

40.8.2 - Multiple Lines of Business - Exceptions

42 CFR 422.2268, 423.2268

Plans/Part D 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 enrollees receiving the non-renewal notice. **CMS considers** additional materials **provided in** a separate enclosure within the same envelope **to be consistent with permitted marketing practices**. Enrollment applications are prohibited from being provided with non-renewal information.

40.8.3 - Marketing Materials from Third Parties that Provide Non-Benefit/Non-Health Services

42 CFR 422.2268, 423.2268

Third parties that provide non-benefit/non-health services ("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's/Part D Sponsor's membership, which is paid for by the Plan/Part D 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 Plans/Part D Sponsors or highlights Plans/Part D Sponsors using CMS statistical data or other research data sources available to them and offers their services and/or materials to the Plans/Part D Sponsors. The Plan/Part D 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 enrollees.

Example C: Materials created by organizations like the Red Cross and Asthma Coalition.

If a non-benefit/non-health service-providing third party wishes to develop and/or provide information to a Plan's/Part D Sponsor's enrollees and/or prospective enrollees, plans must **review such materials and ensure** compliance with the MMG requirements prior to distributing materials to the Plan's/Part D Sponsor's membership. See section [50.13](#).

40.9 - Providing Materials in Different Media Types

42 CFR 422.64, 422.111, 423.48, and 423.128

Plans/Part D Sponsors may provide materials using different media types (e.g., electronic or portable media like email, CD, or DVD). However, Plans/Part D Sponsors must receive consent prior to providing materials in this format (i.e., individuals must opt-in) **in order for the materials to satisfy Medicare notice and disclosure requirements**. When requesting consent, the Plan/Part D Sponsor must specify to the beneficiary the media type and the documents to be sent in such media format.

In addition, Plans/Part D Sponsors electing to provide any materials using different media types must:

- Provide hard copies (**excluding plan web pages**) of all enrollee materials available to enrollees upon request
- Inform enrollees of the option and give them the choice to opt-in. If a enrollee no longer wishes to receive plan communications through electronic or portable media, the enrollee must be able to opt-out upon request
- Document each enrollee's choice of media type and (opt-in) election to receive plan communications using that type
- Have safeguards in place to ensure that enrollee contact information is current, communication materials are delivered and received timely and appropriately, and important materials are identified in a way that enrollees 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)
- Ensure compliance with HIPAA

40.10 - Standardization of Plan Name Type

42 CFR 422.2268 (q), 423.2268 (q), sections 1851(h)(6) and 1860D-4(l)(3)

Plans/Part D Sponsors must include the plan type in each plan's name using standard terminology. Plans/Part D Sponsors enter and maintain their plan names in HPMS. Plans/Part D Sponsors must include the plan type on all marketing materials when the plan name is mentioned.

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/Part D Sponsors **containing** 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 422.2262(c), 422.2264, 423.2262(c), 423.2264

In general, CMS groups marketing materials into two distinct categories – materials directed to potential enrollees and communications to existing enrollees. Unless otherwise noted, the disclaimers described in this section are required on all marketing materials created by the Plan/Part D Sponsor regardless of the intended audience. Disclaimers must be prominently displayed on the material and must be of similar font size and style (refer to section 40.2 for more information).

Disclaimers are not required on call scripts, communications written for social media, banner and banner-like ads, envelopes, and outdoor advertising. However, if a communication written for social media has the potential to be disseminated via another medium, disclaimers must be included. For example, a video produced for YouTube must include disclaimers because the video has the potential to be disseminated by other means.

50.1 - Federal Contracting Disclaimer

42 CFR 422.2264(c), 423.2264(c)

All marketing materials must include a contracting statement either in the text or at the end/bottom of the piece. The statement should include the legal or marketing name, the type of plan (e.g., HMO, PPO, PFFS, PDP), and who the contract is with (e.g., Medicare, Federal Government, State Medicaid program).

Plans/Part D Sponsors are responsible for creating their own disclaimer that meets the requirement specified in the regulation text cited above. An example of this statement follows:

- “[Plan’s/Part D Sponsor’s legal or marketing name] is an HMO plan with a Medicare contract. Enrollment in [Plan’s/Part D Sponsor’s legal or marketing name] depends on contract renewal.”

NOTE: Radio and 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) and (b), 423.128(a) and (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, provider 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(a), 423.128(a)(2), 423.2264(a)

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 enrollees.

50.4 – Disclaimer on Availability of Non-English Translations

42 CFR 422.2264(e), 423.2264(e)

Plans/Part D Sponsors that meet the five (5) percent threshold for language translation (Refer to section 30.5) must place the following alternate language disclaimer on all materials:

- “This information is available for free in other languages. Please call 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 Plan Benefit Packages (PBP) related to the document. 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 – Disclaimer on SNP Materials

42 CFR 422.4(a)(1)(iv), 422.111(b)(2)(iii), 422.2264(a)(4), 423.2264(a)(3)

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.”

Plans/Part D Sponsors may not discuss numeric SNP approval scores in marketing materials or press releases. Plans/Part D Sponsors may only include the following information related to their NCQA SNP approval:

- “[Insert Plan Name] has been approved by the National Committee for Quality Assurance (NCQA) to operate as a Special Needs Plan (SNP) until [insert last contract year of NCQA approval] based on a review of [insert Plan Name’s] Model of Care.”

50.6 – Disclaimer When Cost-Sharing is Mentioned on D-SNP Materials Targeting Potential Enrollees

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

The following disclaimer must be on 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 – Disclaimer for Private Fee-for-Service Plans Targeting Potential Enrollees

PFFS materials targeting potential **enrollees** must include the following disclaimer:

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

50.8 – **Disclaimers for Medicare Medical Savings Accounts (MSAs) Targeting Potential Enrollees**

42 CFR 422.111(b)(2), 422.2264(a)(4), 423.2264(a)(3)

MSA materials targeting potential **enrollees** 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(n), 423.2268(n)

Plans/Part D Sponsors that enter into co-branding relationships with network providers **must** 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 **422.156(b)(2)**, 422.2268(e) and (o), 423.2268(e) and (o)

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 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)

Plans/Part D 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 422.2262(c), 423.2262(c)

Plans/Part D Sponsors 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 non-benefit/non-health service providing third-party entity that is not affiliated or contracted with the Plan/Part D Sponsor. An affiliation is defined as a mutual agreement of understanding (includes, but is not limited to parent organization relationships). Plans/Part D 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.

50.13.1 – Disclaimer When Third Parties List a Subset of Plan Options

42 CFR 422.2264, 423.2264

Plans/Part D Sponsors must ensure that materials developed by a third party providing information on a subset of plan choices that lists, compares, or names available plans, 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.”

50.14 - Disclaimer When Referencing Star Ratings Information

42 CFR 422.2264, 423.2264

Plans/Part D Sponsors must include the following disclaimer on all materials referencing Star Ratings information:

- “Medicare evaluates plans based on a 5-star rating system. Star Ratings are calculated each year and may change from one year to the next.”

50.15 –Pharmacy-Related Disclaimers

If a directory is a subset of a service area, Part D sponsors must advise members that: “This directory is for <geographic area>.”

- If a Part D Sponsor lists pharmacies in its network but outside the service area, the sponsor must advise members that: “We also list pharmacies that are in our network but are outside <geographic area>.”

On marketing materials that mention mail order pharmacies, Part D Sponsors are expected to, when applicable:

- Advise enrollees that they can get prescription drugs shipped to their homes through the network mail order delivery program.
- State the typical number of (calendar or business) days or range of days after the pharmacy receives an order within which enrollees should expect to receive their drugs.
- Provide a phone number for members to call when their mail order drugs do not arrive within the estimated time frames.
- When applicable, advise enrollees that they have they have the choice to sign up for automated mail order delivery.

50.16 – Mailing Statements

42 CFR 422.2268(e), 422.2272(b), 423.2268(e), 423.2272(b)

In order to ensure that beneficiaries can quickly and easily identify the contents of a Plan’s/Part D Sponsor’s mailing, all Plans/Part D 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. Plans/Part D 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/Part D 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 and 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, Plans/Part D Sponsors should categorize it as a plan information mailing.

However, if the mailing contains non-health or non-plan related information (refer to section [160.4](#) for examples), a Plan/Part D Sponsor should use the “non-health or non-plan related information” mailing statement. Plans/Part D Sponsors may not modify these mailing statements and must use them verbatim.

In addition, Plans/Part D Sponsors must include their plan name or logo on every envelope to current and prospective enrollees (either on **or visible from the front of the** 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: Plans/Part D Sponsors are not required to include the material ID on envelopes; however all envelopes must be submitted to HPMS with an associated marketing material ID number.

NOTE: Envelopes containing additional information (e.g., advertising) must be submitted for review.

50.17 – Disclaimer for Other Formulary Documents

The following disclaimer must be displayed prominently on the cover of other formulary documents referenced in section [60.5.4](#):

- “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 - Required Documents

60.1 - Summary of Benefits (SB)

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

The SB is a standardized document that should be generated via HPMS. Plans/Part D Sponsors **must** include the SB when providing an enrollment form and also upon request. Additionally, Plans/Part D Sponsors must provide the multi-language insert any time they distribute an SB (see [30.5.1](#)).

- **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.

The SB must be submitted to CMS as one document under the File & Use process. SBs may not be submitted as a template.

Plans/Part D 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.

Plans/Part D Sponsors offering more than one plan may describe several plans in the same document by displaying the benefits for different plans in separate columns. Since the PBP will only print **introduction and benefit information** for one plan, Plans/Part D Sponsors will have to create a side-by-side comparison matrix for two (or more) plans by manually combining the information into a chart. Plans/Part D Sponsors can use a comparison matrix and still submit the document under File & Use. Plans/Part D Sponsors must also modify the introduction to accurately reflect the plans that have been added to **the benefits information**.

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 Plans/Part D Sponsors must create ID cards following the National Council for Prescription Drug Program (NCPDP) or Workgroup for Electronic Data Interchange (WEDI) standards.

Combination health and drug plan ID cards must follow the WEDI standard and must include the required information in [60.2.1](#) and [60.2.2](#) below.

All Plans/Part D Sponsors must issue and reissue (as appropriate) enrollee ID cards that enrollees may use to access covered services under the plan.

ID cards must include:

- The Plan website address
- The Plan's customer service number

Plans/Part D Sponsors must ensure that the enrollee identification number on the ID card is not the SSN or Healthcare Insurance Claim Number (HICN) of the enrolled enrollee.

Plans/Part D Sponsors must include the CMS contract number and PBP number on the enrollee ID card.

ID cards are not required to include:

- The marketing material identification number
- Hours of operation of the customer service center
- Disclaimers noted in section [50](#)
- Health Plan Identification Number (HPID) (for more information on HPID, review the regulations published by CMS' Office of E-Health Standards and Services (CMS-0040-F). 77 Fed. Reg. 54664 (Sept. 5, 2012), as corrected 77 Fed. Reg. 60629 (Oct. 4, 2012))

(Refer to section [30.2.1](#) regarding co-branding requirements related to ID cards.)

60.2.1 – Health Plan ID Card Requirements

Other than exceptions cited in section [60.2](#), the health plan enrollee ID card (for MA or 1876 cost plans) must meet the standards for medical ID cards in the most recent version of the WEDI Health Identification Card Implementation Guide. Visit www.wedi.org to find the Guide.

Health plan ID cards must also include the phrase "Medicare limiting charges apply" on PPO and PFFS cards only.

60.2.2 – Part D Sponsor ID Card Requirements

Other than any exceptions cited in section [60.2](#), the Part D Sponsor enrollee ID card must meet the most recent version of the 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 Sponsor ID Card must include the Medicare Prescription Drug Benefit Program Mark (Refer to section [150](#) for more information).

60.3 - Additional Materials Enclosed with Required Post-Enrollment Materials

42 CFR 422.111, 423.128

Unless otherwise directed, Plans/Part D 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.). **In addition to complying with all relevant laws and regulations, these materials should** be distinctly separate (e.g., folded or different color pages) from the required document within the mailing envelope, and may not include advertising materials (e.g., materials advertising additional products such as Medigap by the Plan/Part D Sponsor).

NOTE: Additional materials may not be included in the ANOC/EOC mailing unless otherwise specified (**e.g., ANOC/EOC instructions**).

60.4 - Directories

42 CFR 422.111(b)(3)(i), 422.111(e), 423.128(b)(5), 422.2260, 423.2260, **422.2262(c), 423.2262(c)**

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

MAPD 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.

MA, MAPD, Part D, and 1876 cost plans must include information regarding all contracted network providers and/or pharmacies in directories at the time of enrollment. 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 enrollees 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 that are generally applicable to all MA and PDP plans.

Plans must, and Part D Sponsors are expected to, 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, **whether the termination was for or without cause. When a contract termination involves a primary care provider, all enrollees who are patients of that primary care provider must be notified. For other provider types, all enrollees who regularly use the provider/pharmacy's services must be notified.**

Plans/Part D Sponsors should include the following information in the written notice of termination of a contracted provider, when practicable:

- **Names and phone numbers of in-network providers that enrollees may access for continued care;**
- **Information regarding how enrollees can request continuation of ongoing medical treatment or therapies with their current providers; and**
- **Customer service number(s) where answers to questions about the network changes will be available.**

Plans/Part D Sponsors should develop detailed scripts, call center talking points and frequently asked questions so they can effectively respond to phone inquiries from enrollees and other stakeholders.

In instances where it has been determined there are significant changes to the provider/pharmacy network occur, the organization should send a special mailing immediately.

See section [100](#) for additional website requirements.

60.4.1 - Pharmacy Directories

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

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.

Part D Sponsors must advise beneficiaries that they generally must use network pharmacies to receive plan coverage. If the network consists of **pharmacies with preferred cost-sharing in addition to pharmacies with standard cost-sharing**, the sponsor must identify the pharmacies **that offer preferred cost-sharing** and **note** that enrollees may save on cost-sharing at **those** pharmacies. For more information, visit Chapter 5 of the Prescription Drug Benefit Manual, section 50.9 (<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html>).

The pharmacy directory must advise enrollees that they can either visit the website or call the plan for additional information and provide contact information on both the front and back cover pages.

60.4.1.1 – Information about Pharmacies

The pharmacy directory must:

- Provide the pharmacy name, address, and phone number for all network pharmacies except:
 - For chain pharmacies, Part D Sponsors have the option to 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, Part D 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, Part D Sponsors are instructed to list the TRS Relay number 711. Part D Sponsors should not list their own customer service number as a pharmacy phone number or TTY number.
- Identify type of pharmacy (e.g., retail, mail order, long-term care, home infusion, I/T/U)
- Identify which pharmacies provide an extended day supply of medications
- 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 model.

Part D Sponsors are expected to consult sections 50.15 - Pharmacy-Related Disclaimers.

60.4.2 - Provider Directories

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

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

Plans may print a separate directory for each sub-network and disseminate this information to enrollees 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 enrollees upon request.

Plans may publish separate PCP and specialty directories provided both directories are given to enrollees at the time of enrollment.

60.5 - Formulary and Formulary Change Notice Requirements

42 CFR 423.120(b)(5), 423.128 (b)(4) , 423.2262(a), 423.2268(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. While the print version of the formulary may be abridged, each Part D Sponsor must provide a comprehensive formulary on its website. See Chapter 6 of the Prescription Drug Benefit Manual for program guidance regarding formularies, change notices, and utilization management (<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html>).

Part D Sponsors **must** ensure that each formulary marketed for a specific plan is consistent with the HPMS formulary file approved by CMS for that plan:

- 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.

A Part D Sponsor may market enhancements (such as adding a newly available drug to the formulary), but not negative changes, to its formulary prior to receiving CMS approval. For more details, see Chapter 6 of the Prescription Drug Manual, section 30.3 (<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html>).

In the event that a marketing discrepancy is identified, the Part D Sponsor must continue to cover the drug(s) at the more favorable cost share or with less restrictive utilization management for the affected enrollee (as defined in 42 CFR 423.100) through the end of the contract year.

60.5.1 - Abridged Formulary

42 CFR 423.128, 423.2262(c), 423.2268(e)

Part D Sponsors are expected to provide abridged formulary document that includes at a minimum:

- 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
- Advise enrollees that the document includes a partial list of drugs; that enrollees can visit the website or call the plan for a complete list of covered drugs
- Contact information on both the front and back cover pages
- The following statement: "Note to existing enrollees: This formulary has changed since last year. Please review this document to make sure that it still contains the drugs you take."
- 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 Sponsor’s formulary document
- The following statement: “<Part D Plan Sponsor 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 Sponsor’s general utilization management procedures
- A statement that if a drug is not on the formulary, enrollees may contact the Part D sponsor to obtain a list of alternatives or to apply for exceptions to coverage rules
- An explanation of how to obtain an exception to the Part D Sponsor’s formulary, utilization management tools or tiered cost sharing
- A description of the Part D Sponsor’s drug transition policy
- A statement that enrollees may contact the Part D Sponsor for additional information or questions on the formulary
- A chart (the CMS-approved 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 Sponsor formulary.

NOTE: While Part D Sponsors must ensure that at least two drugs per therapeutic class are included within the abridged formulary, Part D Sponsors 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 Sponsors 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 section 60.5 may not be included in the abridged formulary document.
- Tier Placement: Part D Sponsors 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 Sponsors may also choose to include a column providing the co-payment or co-insurance amount for each tier.

- Utilization Management (UM): Part D Sponsors 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 Sponsor may choose to designate a prior authorization on a drug by placing an asterisk next to the name of the drug.

NOTE: Every beneficiary must be able to tell by examining the **complete** formulary whether a specific drug is covered—including those drugs that have varying dosage forms or strengths at different formulary statuses, tier placements, and/or utilization management procedures (e.g., prior authorization, step therapy, quantity limit, or other restrictions). If there are differences in formulary status, tier placement, quantity limit, prior authorization, step therapy, or other restrictions for a drug based on its differing dosage forms or strengths, the formulary must clearly identify how it will treat the different formulations of that same 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
- A symbol or abbreviation, as well as an explanation, to identify any 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)
- Part D Sponsors may not include OTC drugs in the formulary table, but are expected to provide a separate list or table

60.5.2 - Comprehensive Formulary

42 CFR 423.4, 423.120, 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 Sponsor (for instance, drugs covered as an enhancement) and would not inform beneficiaries that they can obtain a comprehensive formulary by contacting the Part D Sponsor. 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 section [60.5](#).

60.5.3 - Changes to Printed Formularies

42 CFR 423.120(b), 423.128(a)-(c)

Part D Sponsors will be expected to update all impacted abridged and comprehensive printed formularies with any applicable formulary changes.

Part D Sponsors may make any necessary formulary changes via errata sheets mailed to affected enrollees. 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 **non-maintenance** formulary changes have occurred and that affected enrollees 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 enrollee's physician and was not removed for safety reasons. Refer to the Prescription Drug Manual, Chapter 6, sections 30.3.3.3 and 30.3.4.1. This requirement does not extend to mid-year maintenance changes defined in section 30.3.3.2 of the Prescription Drug Manual (<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html>). 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 Sponsors 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 and include the disclaimer in section [50.17](#).

60.5.5 - Provision of Notice to Beneficiaries Regarding Formulary Changes

42 CFR 423.120(b)(5)

Part D Sponsors must provide at least sixty (60) days' notice or a 60-day supply with notice to affected beneficiaries before removing a Part D drug from the Part D Sponsor'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. Sixty day notice must be provided in writing unless a beneficiary has affirmatively elected to receive electronic notice. In such instances, Part D Sponsors can determine the most effective means by which to communicate the 60-day notice of formulary change information to beneficiaries, including electronic means. Part D Sponsors should refer to Chapter 6 of the Prescription Drug Manual, section 30.3.4 (<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html>).

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 Prescription Drug Benefit Manual, Chapter 6, section 30.3.4.2 of (<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html>).

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 Part D 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 Part D Sponsor when retroactive changes apply to prior benefit year prescription fills. For example, a plan's final EOB for CY 2013 must be sent in January 2014, for December 2013 fills. Once the final EOB for CY 2013 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, 2013).

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 Plans/Part D Sponsors must send the ANOC/EOC for enrollee 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. Additional materials may not be included in the ANOC/EOC mailing unless otherwise specified (**e.g., in the ANOC/EOC instructions**). Stand-alone EOCs do not need to be resubmitted in HPMS.

D-SNPs may choose to send the ANOC for enrollee receipt by September 30, and the EOC for enrollee 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 enrollee receipt by September 30 are not required to send an SB to current enrollees.

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

Employer/union group plans must send the ANOCs and EOCs for enrollee 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 Plans/Part D Sponsors are mailing their ANOC/EOC timely, Plans/Part D Sponsors must indicate the actual mail date in HPMS within 15 days of mailing. **This includes mail dates for alternate materials.** Plans/Part D 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.

Plans/Part D Sponsors must use the standardized ANOC/EOC errata model to correct any errors and must submit the errata model for review via HPMS. Plans/Part D Sponsors must ensure corrected versions of the **ANOC and EOC** are on their websites. Plans/Part D Sponsors are not required to post the ANOC/EOC errata model on websites.

60.8 – Other Mid-Year Changes Requiring Enrollee Notification

42 CFR 422.111(d)(3)

CMS requires beneficiary notification of mid-year benefit changes. Examples of changes include formulary changes, National Coverage Determination (NCD) changes, plan rule changes, or provider network changes. Plans/Part D Sponsors should refer to the appropriate guidance for the requirements of each change. (For more information visit: http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?list_type=nca; <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html>).

For instance, the Plan may use a variety of mechanisms to inform enrollees of these changes in coverage. 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. Plans may **also** choose to provide this information to enrollees via email or one-time mailings specific to this issue. NCD communications do not need to be submitted in HPMS.

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

70.1 - Promotional Activities

42 CFR 422.2268, 423.2268

Generally, promotional activities are designed to attract the attention of prospective enrollees and/or encourage retention of current enrollees. In addition to the guidance on nominal gifts, any promotional activities or items offered by Plans/Part D Sponsors:

- Must have only nominal value (be worth **no more than** \$15) based on the fair market value of the item 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 be tied directly or indirectly to the provision of any other covered item or service.

NOTE: Plans/Part D Sponsors should track and document items given to current enrollees. Plans/Part D 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.

70.1.1 - Nominal Gifts

42 CFR 422.2268(a-c), 423.2268(a-c)

Plans/Part D Sponsors may offer gifts to potential enrollees as long as the gifts are of nominal value and provided regardless of enrollment.

The following rules must be followed when providing gifts:

- If a nominal gift is one large gift (e.g., a concert, raffle, drawing), the total fair market value must nominal per person (be worth \$15 or less when it is divided by the estimated attendance). For planning purposes, anticipated attendance may be used, but must be based on actual venue size, response rate, or advertisement circulation.
- Nominal gifts may not be in the form of cash or other monetary rebates, even if their worth is \$15 or less. 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: Plans/Part D Sponsors should refer to the Office of Inspector General's website regarding advisory opinions on gift cards.

70.2 - Rewards and Incentives

42 CFR 422.2268

Plans may include information about Reward and Incentive Programs in marketing materials, as long as those communications are provided to all current and prospective enrollees without discrimination based on race, national origin, gender, disability, chronic disease, whether a person resides or receives services in an institutional setting, or other prohibited basis. Further, when marketing Reward and Incentive Programs to potential enrollees, plans must do so in conjunction with Plan benefits.

Plans offering Nominal Gifts as part of a Promotional Activity are outside of Rewards and Incentives and must follow the guidance in section 70.1 and 70.1.1.

70.3 - Exclusion of Meals as a Nominal Gift

42 CFR 422.2268(p), 423.2268(p)

Plans/Part D Sponsors may not provide or subsidize meals at sales/marketing events. However, Plans/Part D Sponsors may provide refreshments and light snacks. Plans/Part D Sponsors should use their best judgment on the appropriateness of food products provided and should 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 section [70.1.1](#).

70.4 - Unsolicited **Electronic Communication Policy**

42 CFR 422.2268(d) 423.2268(d)

A Plan/Part D Sponsor may not **initiate separate electronic, or otherwise, contact (e.g., email, direct message)** unless an individual has agreed to receive those communications. **If an individual comments, likes or follows a Plan/Part D Sponsor on social media, this does not constitute agreement to receive Plan/Part D Sponsor communications outside of the public forum. Plans/Part D Sponsors may not initiate separate communications to specific social media users. Pop-ups or targeted advertisements are permitted.**

In addition, Plans/Part D Sponsors may respond to a question or statement initiated by the beneficiary, but may not address subjects beyond the scope of the question or statement.

Plans/Part D Sponsors are prohibited from renting **or** purchasing e-mail lists to distribute information about MA, PDP, or section 1876 cost plans, **and** may not **send electronic communications to** individuals at e-mail addresses **or on social media** obtained through friends or referrals.

Plans/Part D Sponsors must provide an opt-out process for enrollees to no longer receive e-mail communications.

70.5 - Marketing through Unsolicited Contacts

42 CFR 422.2268(d), 423.2268(d)

In general, Plans/Part D Sponsors may not market through unsolicited direct contact, 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 that becomes a “no-show” may leave information at the no-show beneficiary/individual’s residence.

The prohibition on marketing through unsolicited contacts does not extend to **conventional** 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.

70.6 - Telephonic Contact

42 CFR 422.2268(d)-(f), 423.2268(d)-(f)

Agents may contact their own clients and Plans/Part D Sponsors may contact current enrollees at any time 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/Part D Sponsor, the agent or Plan/Part D Sponsor may provide contact information such as a business card that the individual may give to the friend or family enrollee. Otherwise, as instructed in section [30.9](#), a referred individual needs to contact the plan or agent/broker directly.
- Calls to former enrollees who have disenrolled, or to current enrollees who are in the process of voluntarily disenrolling (except as permitted below), to market plans or products. Enrollees 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 (**the Plan/Part D Sponsor must have** documentation of permission to be contacted)
- Calls to beneficiaries to confirm receipt of mailed information, except as permitted below

Plans/Part D Sponsors may do the following:

- Call beneficiaries who submit enrollment applications to conduct quality control and agent/broker oversight activities
- Call their enrollees or use third-parties to contact their current enrollees **about the MA/Part D plans**. Examples of allowed contacts include, but are not limited to, calls to enrollees aging-in to Medicare from commercial products offered by the same organization and calls to an organization's existing Medicaid plan enrollees to talk about its Medicare products.
- Call their enrollees to discuss educational events
- Call their enrollees to conduct normal business related to enrollment in the plan, including calls to enrollees who have been involuntarily disenrolled to resolve eligibility issues
- Call former enrollees 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 enrollees 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 business reply card (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
- Call their enrollees via an automated telephone notification to inform them about general plan information such as the AEP dates, availability of flu shots, upcoming plan changes, and other important plan information

70.7 - Outbound Enrollment and Verification Requirements

42 CFR 422.2272(b), 423.2272(b)

Plans/Part D Sponsors are required to maintain a system to ensure beneficiaries are enrolled into the plan they requested and understand the rules applicable to that plan. This system must be maintained for all

enrollments, including enrollment requests in which an independent or employed agent/broker provided plan-specific information to the individual, thus potentially influencing the individual's plan choice and/or assisting in a subsequent enrollment request.

Plans/Part D Sponsors have the option to complete the enrollment verification process by telephone, email (if beneficiary opted-in for email) or direct mail. The beneficiary must be contacted within fifteen (15) calendar days of receipt of the enrollment request. Plans/Part D Sponsors may integrate enrollment verification into existing practices, such as welcome calls without making a separate call for enrollment verification. If the plan chooses to utilize a telephonic contact but is unable to speak with the individual directly, the plan must either continue call attempts or follow up with a written communication.

The timing and method of contact must be documented and the following information should be provided:

- Introduction and plan name
- Reason for call, email or letter
- Confirmation of receipt of application into plan (specific plan name)
- Request additional information if needed to complete the enrollment request
- Explanation as to how plan works (e.g. HMO, PFFS, Section 1876 Cost)
- Inform beneficiary that additional enrollment material is forthcoming, including ID card
- Provide at least two cost sharing/coinsurance examples, such as PCP and Specialists visits.
- Monthly premium (LIS and non-LIS)
- Explain physician/pharmacy network may change and may find an up-to-date list on the Plan/Part D Sponsor's website
- Explain that beneficiary may cancel enrollment within seven (7) calendar days from the date of the email, letter or phone call or by the day before the enrollment effective date, whichever is later. For AEP enrollment requests, the cancellation date is December 31. (For more details on the election periods that apply in this situation, see Chapter 2 and Chapter 3 section 30 <http://www.cms.gov/Medicare/Eligibility-and-Enrollment/MedicareMangCareEligEnrol/>)

- Offer to address basic questions regarding cost-sharing for PCP and specialists office visits
- For beneficiaries enrolled in Part D: Explain pharmacy access and drug formulary

The following agent/broker-assisted enrollments are excluded from the enrollment verification process:

- Enrollments into employer or union sponsored plans
- Enrollments from one plan to another plan 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)

Plans/Part D Sponsors are not expected to delay processing the enrollment request (including, but not limited to, activation of benefits and submission of enrollment request data to CMS) while completing the enrollment verification process. If the enrollment request is incomplete upon initial receipt, Plans/Part D Sponsors are expected to conduct the enrollment verification process while attempting to obtain the information needed to complete the enrollment request.

Enrollment verifications are expected to be made to the applicant after the sale has occurred and not at the point of sale. The Plan/Part D Sponsor is expected to ensure that enrollment verifications are not conducted by sales agents. Also, if calling or emailing applicants, Plans/Part D Sponsors are expected to ensure that sales agents are not physically present with the applicant at the time of the verification. Plans/Part D Sponsors may not use automated calling technologies to conduct enrollment verifications via telephone; CMS expects enrollment verification calls to be interactive.

If the Plan/Part D Sponsor makes a determination to deny an enrollment request because the individual is ineligible to enroll prior to completing the enrollment verification process, it is expected to discontinue the process and instead inform the individual of his or her ineligibility. If the Plan/Part D Sponsor receives a transaction reply report (TRR) from CMS rejecting the enrollment prior to completing the enrollment verification process, it is expected to suspend the process, but must resume if the Plan/Part D Sponsor determines the rejection to be erroneous, such that the enrollment will be resubmitted to CMS.

70.8 – Prospective Enrollee 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/Part D 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 **for prospective enrollees** 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 Plans/Part D 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, Plans/Part D 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 **a prospective enrollee** 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 Plans/Part D 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

At educational events, Plans/Part D 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).

These activities constitute prohibited sales activities at educational events.

70.8.1 – Enrollee-Only Educational Events

§ 1851(j)(1)(D), 42 CFR 422.2268(I), 423.2268(I)

Plans/Part D Sponsors that hold enrollee-only educational events may not conduct enrollment or sales activities, as described in 70.8, during these events. However, Plans/Part D Sponsors may discuss plan-specific premiums and/or benefits and distribute plan-specific materials to enrollees.

Educational events must be explicitly advertised as “educational;” otherwise they will be considered by CMS as sales/marketing events. In this context only (i.e., events for existing enrollees only), this discussion of benefits is not considered a sales activity. Any marketing of these events must be done in a way that reasonably targets only existing enrollees (e.g., direct mail flyers), not the mass marketplace (e.g., radio or newspaper ad).

70.9 - Marketing/Sales Events and Appointments

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/Part D 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/Part D Sponsor representative who can discuss the merits of the plan's products.

- Plans/Part D 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, Plans/Part D 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

70.9.1 – Notifying CMS of Scheduled Marketing Events

42 CFR 422.2268, 423.2268, 422.504(f)(2), 423.505(f)(2)

Plans/Part D Sponsors must notify CMS of 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. 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.

If a sales event is canceled before its originally scheduled date and time, the Plan/Part D Sponsor must cancel the event in HPMS, more than forty-eight (48) hours prior to the originally scheduled date and time of the event, whenever possible.

70.9.2 - Personal/Individual Marketing Appointments

42 CFR 422.2268(f)-(h), 423.2268(f)-(h)

Personal/individual marketing appointments typically take place in the 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 section [70.9.3](#)).

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

The Plan's/Part D Sponsor's representative may not do the following:

- Discuss plan options that were NOT agreed to by the 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

70.9.3 - Scope of Appointment

42 CFR [422.2262](#), 422.2268(g) and (h), [423.2262](#), 423.2268 (g) and (h)

When conducting marketing activities, a Plan/Part D Sponsor may not market any health care related product during a marketing appointment beyond the scope that the beneficiary agreed before the meeting with that individual. The Plan/Part D Sponsor must document the scope of the agreement before the appointment. Distinct lines of plan business include MA, PDP and Cost Plan products. If a Plan/Part D Sponsor would like to discuss additional products during the appointment that the beneficiary did not agree to discuss in advance, they must document it 48 hours in advance, when practicable. If it is not practicable and the beneficiary requests to discuss other products, the Plan/Part D Sponsor must document a second scope of appointment for the additional product type to continue the marketing appointment.

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. Plans/Part D Sponsors are encouraged to use a variety of technological means to fulfill the scope of appointment requirement, including, **but not limited to**, conference calls, fax machines, designated recording line, pre-paid envelopes, and e-mail
- **Plans/Part D Sponsors are expected to include the following when documenting the SOA:**
 - **Product type (e.g. MA, PDP) that the beneficiary has agreed,**

- Date of appointment,
 - Beneficiary contact information (e.g. name, address, telephone number),
 - Signature (e.g. beneficiary or authorized representative),
 - The SOA must include the type of product (e.g. MA, PDP) the beneficiary has agreed to discuss during the appointment,
 - Method of contact (e.g. walk-in),
 - Agent information (e.g. name and contact information) and signature,
 - A statement that beneficiaries are not obligated to enroll in a plan; their current or future Medicare enrollment status will not be impacted and clearly explain that the beneficiary is not automatically enrolled in the plan(s) discussed, and
 - If the SOA was not signed prior to the appointment, include an explanation why it was not completed.
- 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 for review and approval. . Additionally, Plans/Part D 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.

NOTE: Marketing/sales events, as defined in section [70.9](#), do not require documentation of beneficiary agreement.

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

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

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

70.10 - PFFS Plan Provider Education and Outreach Programs

42 CFR 422.114, [422.202](#)

PFFS Plans should 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 should 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.

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

42 CFR 422.114, [422.202](#)

HPMS allows PFFS plans to directly provide CMS with their plan terms and conditions of payment contact and website information. All PFFS Plans must complete the data entry for these fields in HPMS and update the information as needed in order for CMS to make the determinations required under 42 CFR 422.114.

The “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.

The “PFFS Terms and Conditions of Payment website” field should be populated with the web address for where the Plan 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.

70.11 - Marketing in the Health Care Setting

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

We recognize that Plans/Part D Sponsors have agreements with providers in connection with plan activities and expect those agreements to address marketing activity in a manner consistent with Medicare regulations. These requirements are discussed throughout this section. Plans/Part D Sponsors and providers with whom they have a relationship (contractual, **co-branding** or otherwise) who assist beneficiaries with plan selection should ensure that provider assistance results in plan selection that is always in the best interest of the beneficiary.

Plans/Part D 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 from or interact with pharmacy providers and obtain medications.

Plans/Part D Sponsors are prohibited from conducting sales presentations, distributing and accepting enrollment applications, and soliciting Medicare beneficiaries in areas where patients primarily 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.

Plans/Part D 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. Plans/Part D Sponsors may use providers to make available and/or distribute plan marketing materials as long as the provider and/or the facilities distributes or makes available Plan/Part D Sponsor marketing materials for all plans with which the provider participates. CMS does not expect providers to proactively contact all participating plans; rather, **a Plan/Part D Sponsor must only ensure that** a provider agrees to make available and/or distribute plan marketing materials and accept future requests from other Plans/Part D Sponsors with which **the providers** participate. Plans/Part D Sponsors may also provide materials for providers to display posters or other materials in common areas such as the provider's waiting room. Additionally, Plans/Part D Sponsors may provide materials to long-term care facilities to provide materials in admission packets announcing all plan contractual relationships.

SNP plans may provide to long term care facility staff, **for distribution to** 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 **request** a meeting or additional information.

70.11.1 - Provider-Based Activities

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

CMS is concerned with Plans/Part D Sponsors engaging in provider-based marketing activities because:

- 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/Part D Sponsor representative

We recognize that Plans/Part D Sponsors have agreements with providers in connection with plan activities and expect those agreements to address marketing activity in a manner consistent with Medicare regulations. This includes ensuring that if a provider advertises non-health related items or services, the advertisement makes it clear that those items/services are not covered by the Plan/Part D Sponsor. To the extent that the Plan/Part D Sponsor ensures that a provider assists a beneficiary in an objective assessment of his/her needs and potential options to meet those needs, the Plan/Part D Sponsor may use providers for such activities. Plans/Part D Sponsors may allow contracted providers to engage in discussions with beneficiaries should a beneficiary seek advice. However, Plans/Part D Sponsors must ensure, through their agreements with providers, that contracted providers are advised of the need to remain neutral when assisting with enrollment decisions and that providers do not:

- Offer scope of 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 Plans/Part D 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

Plans/Part D Sponsors may **use and** allow contracted providers to:

- Provide the names of Plans/Part D Sponsors with which they contract and/or participate (see section [70.11.2](#) for additional information on provider 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

70.11.2 – New or Continued Provider Affiliation Announcements

42 CFR 422.2262(a), 422.2268, 423.2262(a), 423.2268

Plans/Part D Sponsors **may permit their providers to** announce new or continuing affiliations **between providers and** specific Plans/Part D Sponsors through general advertising (e.g., radio, television, websites). **Plan/Part D Sponsor materials (including materials provided to providers) that describe plan benefits, premiums, or cost sharing must be submitted through HPMS. Materials that only announce the affiliation or continuing affiliation do not need to be submitted through HPMS.**

New Affiliations

A new affiliation announcement **may be made once** within the first 30 days of a new contract agreement **(in these announcements, Plans/Part D Sponsors may allow contracted providers to name only one Plan/Part D Sponsor)**. This may be done through direct mail, e-mail, by telephone, or advertisement. **Neither the Plan/Part D Sponsor nor the contracted provider needs to notify beneficiaries that the provider may contract with other Plans/Part D Sponsors.**

Continuing Affiliations

Continuing affiliation announcements may be made through direct mail, e-mail, phone or advertisement. Continuing affiliation announcements must clearly state that the provider may also contract with other Plans/Part D Sponsors.

70.11.3 - SNP Provider Affiliation Information

42 CFR 422.2268, 423.2268

Plans/Part D Sponsors may allow contracted providers to 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 and must include the appropriate disclaimer (refer to section [50](#)). 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.

70.11.4 - Comparative and Descriptive Plan Information

42 CFR 422.2268, 423.2268

Plans/Part D Sponsors may allow contracted providers to distribute printed information provided by a Plan/Part D Sponsor to their patients comparing the benefits of all of the different plans with which they contract. Materials must include the appropriate disclaimer (refer to section [50](#)). Materials may not "rank order" or highlight specific plans and should include only objective information. Such materials **should** have the concurrence of all Plans/Part D Sponsors involved in the comparison and must be approved by CMS prior to distribution (i.e., these items are not be subject to File & Use). The Plans/Part D Sponsors must determine a lead Plan to coordinate submission of these materials to CMS for review (refer to section [90.2](#) for more information on submission of marketing materials).

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

42 CFR 422.2268, 423.2268

Plans/Part D Sponsors may allow contracted providers to distribute printed information comparing the benefits of different Plans/Part D 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 section [40.8.3](#).

80 - Telephonic Activities and Scripts

80.1 - Customer Service Call Center Requirements

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

Plans/Part D Sponsors must operate a toll-free call center for both current and prospective enrollees **open during usual business hours; we consider** 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) **to be the business hour time frame for plans**. Current and prospective enrollees must be able to speak with a live customer service representative. Plans/Part D Sponsors may use alternative technologies on Thanksgiving and Christmas Day. For example, a Plan/Part D 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, Plans/Part D 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 section [80.2-80.4](#). **If callers are transferred to a third party for provision of the information listed in 80.2 and 80.4, all other requirements in 80.1 apply to the third party.**
- Follow an explicitly defined process for handling customer complaints
- Provide interpreter service to all non-English speaking and limited English proficient beneficiaries
- Inform callers that interpreter services are “free”
- Provide TTY service to all hearing impaired beneficiaries
- 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 4](#).

80.2 – Requirements for Informational Scripts

42 CFR 422.111(c), 422.2262, 422.2264, 422.2264(e), 423.128(c), 423.2262, 423.2264, 423.2264(e)

Informational scripts may not ask the beneficiary if s/he wants to be transferred to a sales/enrollment department nor can the Plan's/Part D 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 transfer to the appropriate sales/enrollment department) at the 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.

Plans/Part D Sponsors are not required to enter informational scripts into HPMS. However, they must retain all scripts and make them available upon request to CMS. Informational scripts must be written in a way that does not mislead or confuse Medicare beneficiaries or misrepresent the Part D Sponsor. At a minimum, Plans/Part D Sponsors must develop scripts that respond to inquiries from prospective and current enrollees about the following subjects:

- Best Available Evidence (BAE) policy (applicable to Part D Sponsors)
- Request for pre-enrollment information
- Benefit information
- Cost-sharing information
- Formulary information
- Pharmacy information, including whether a beneficiary's pharmacy is in the Part D Sponsor's network
- Provider information, including whether a beneficiary's physician is in the Plan's network
- Out-of-network coverage
- Claims submission, processing and payment

- Formulary transition process
- Grievance, organization/coverage determination (including exceptions) and appeals process
- Information on extra help, including how the beneficiary can obtain extra help
- Current TROOP status (for Part D Sponsors and MA-PDPs)
- Information on how to obtain needed forms
- Information on replacing an enrollee identification card
- Service area information

Plans/Part D Sponsors may NOT:

- Include information about other lines of business in scripts

NOTE: Plans/Part D Sponsors can ask if the caller would like to receive information about other lines of business offered by the Plan/Part D 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 enrollee

NOTE: Plans/**Part D Sponsors** may not transfer outbound calls to inbound lines for telephone enrollment. **Enrollment by telephone is limited to calls initiated by the beneficiary (i.e., "inbound" calls). If a beneficiary requests enrollment over the telephone, the agent can provide information as to how the beneficiary can enroll in the plan telephonically. Alternatively, the agent may set up a face-to-face appointment with the beneficiary for application assistance.**

80.3 - Requirements for Enrollment Scripts/Calls

42 CFR 422.60 (c), 423.32 (b)

Plans/Part D Sponsors **must** enter enrollment scripts into HPMS. 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.).

Telephone enrollment scripts must be submitted in their entirety (bullets or talking points are not acceptable). In developing and submitting enrollment scripts, Plans/Part D Sponsors must:

- Follow all requirements described in the CMS Eligibility and Enrollment Guidance in Chapters 2 and 17d of the Medicare Managed Care Manual, as well as 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 enrollment and verification calls (refer to section [70.7](#)).

80.4- 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 to HPMS verbatim (bullets or talking points are unacceptable). Plans/Part D Sponsors must follow all telephone guidance in marketing through unsolicited contacts as noted in sections [70.4](#) and [70.5](#). 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/Part D Sponsor Responsibilities

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

Plans/Part D Sponsors **must** conduct a quality check and ensure 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

Plans/Part D Sponsors **must** submit materials for review through the Marketing Module of 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. **Plans should refer to the User Guide for any questions regarding the Marketing Module or how to submit marketing materials in 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/Part D Sponsor will be required to correct those materials for prospective enrollees and send errata sheets/addenda/reprints to current enrollees within a reasonable timeframe. If CMS finds that the Plan/Part D Sponsor failed to comply with applicable rules and guidance, CMS 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 Alternate Formats

42 CFR 422.2262, 422.2264(e), 423.2262, 423.2264(e)

Non-English **and alternate format** materials must be based on previously approved English versions of the same material. **Plans should submit non-English and alternate format versions after the original English version has a status of approved or deemed in HPMS, or after five (5) calendar days if the original English version is a File & Use document.**

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

See Appendix 1 for a definition of alternate format materials.

90.2.2 - Submission of Websites for Review

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

Plans/Part D Sponsors must submit all **required website content listed in section 100** for review. Plans/Part D Sponsors should submit their websites via links in a Word document. CMS expects reviewers to have an opportunity to review the information **as it will be displayed on the website. The link may provide access to a live website or a test website, provided that the test site displays information as it will appear to the beneficiary/consumer.** 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 to request and receive permission to submit information other than through a live link.

Once a Plan's/Part D Sponsor's website is reviewed and approved in its entirety, a Plan/Part D 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.

Plans/Part D Sponsors may make the website available for public use during the CMS review period; however, Plans/Part D Sponsors must include the status of pending on their website until CMS has either approved or disapproved it. **If the website or portions of the website are disapproved, Plans/Part D Sponsors must submit the revision within 20 days for CMS review.**

Plans/Part D Sponsors are not required to resubmit materials that have received prior approval for posting on their website. Any documents that require submission to HPMS should not be posted on the website until they are approved or accepted.

See section 100 for required website content.

90.2.3 – Submission of Multi-Plan Materials

42 CFR 422.2262, 423.2262

Multi-Plan Materials are those materials that are created by a third-party on behalf of several Plans/Part D Sponsors (e.g., a PBM who creates a Part D EOB that will be used by multiple Part D Sponsors). Plans/Part D Sponsors must follow

these procedures when submitting multi-plan marketing materials. Plans/Part D 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 Plans/Part D 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 Plans/Part D Sponsors with which it contracts
- **Lead Plan/Part D Sponsor (LP)** -- Contracted Plan/Part D Sponsor that submits the Primary Material for CMS review
- **Non-Lead Plan/Part D Sponsor (NLP)** -- Contracted Plan/Part D Sponsor that produces and submits to CMS the Auxiliary Material, based on the approved Primary Material

The CE develops marketing materials in accordance with CMS requirements and coordinates with the 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). Upon approval, the LP will inform the CE, who then provides the NLPs with the primary material's material ID and submission code, so the NLPs may upload their auxiliary materials 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 MCE 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 Plan/Part D Sponsor 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 three parts: the Plan's/Part D Sponsor's contract number; the word "MULTIPLAN;" and any series of alpha numeric characters chosen at the discretion of the Plan/Part D Sponsor.

If material is disapproved, the CE must resubmit disapproved pieces through the same LP.

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 material ID should be identical to the previously approved/accepted "Primary" material, with the exception of the NLP's contract number used in place of the LP's contract number.

NLP multi-plan auxiliary marketing materials submitted for CMS review may not be used until approval from the Plan's/Part D Sponsor's CMS reviewer is received. Materials submitted File & Use may not be distributed until the five (5) calendar day waiting period has passed.

NOTE: There may be instances where a CE wants to use a material for a Plan/Part D Sponsor not identified in the original LP submission (e.g., if the CE solidifies a contract with a new Plan/Part D Sponsor). 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 - HPMS Material Statuses

42 CFR 422.2262, 423.2262

All marketing materials in HPMS have a status: accepted, approved, disapproved, deemed, withdrawn, alternate format, SA/LIS, and/or populated template.

90.3.1 - Approved

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/Part D Sponsor. However, CMS may at any time require a Plan/Part D 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, a Plan's/Part D Sponsor's marketing material dispositions will be considered "conditionally" approved.

90.3.2 - Disapproved

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 in HPMS.

90.3.3 - Deemed

42 CFR 422.2262(a)(1), 423.2262(a)(1), 422.2266, 423.2266

If CMS does not approve or disapprove marketing materials within the specified review time frame, the materials are deemed approved and 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
- Plans/Part D 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/Part D Sponsor may use the material.

90.3.4 - Withdrawn

42 CFR 422.2262, 423.2262

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

90.3.5 - Accepted

CMS acceptance of a material submission indicates that the material was submitted as File & Use and is accepted for use in the format in which it was submitted. It may be distributed by a Plan/Part D Sponsor five (5) calendar days after the date of submission. However, CMS may at any time require a Plan/Part D Sponsor to change any previously accepted marketing materials if found to be inaccurate, altered, or otherwise non-compliant.

90.3.6 - Alternate Format, SA/LIS, and Populated Template

42 CFR 422.2262, 423.2262

These three HPMS material statuses apply to special categories of material. Please see the HPMS User Guide for an explanation of when these statuses are applicable.

90.4 - Resubmitting Previously Disapproved Pieces

42 CFR 422.2262, 423.2262

To expedite the review of previously disapproved pieces, Plans/Part D Sponsors should clearly indicate all changes/updates made to a material when it is resubmitted. Plans/Part D Sponsors may meet this requirement by highlighting any text changes and/or inserting notes to altered areas on the material. Plans/Part D 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 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 Process

42 CFR 422.2262(b), 423.2262(b)

Plans/Part D 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.

A Plan/Part D Sponsor may submit File & Use materials prior to executing a contract with CMS. By executing the CMS contract, the appropriate officer of the Plan/Part D Sponsor is attesting to his/her Plan’s/Part D Sponsor’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)

Plans/Part D Sponsors using File & Use must submit at least ninety (90) percent of marketing materials that qualify for File & Use under this process; meaning that they cannot request a manual review of 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).

90.6.2 - Loss of File & Use Certification Privileges

42 CFR 422.2262(b), 423.2262(b)

A Plan/Part D Sponsor may lose File & Use Certification status or face compliance action if it:

- Submits or uses materials that do not meet the requirements of this chapter; **or**

- Fails to file material(s) at least five (5) calendar days prior to distribution or publication.

If CMS revokes a Plan's/Part D Sponsor's File & Use Certification privileges, the Plan/Part D 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 model materials that are optional for use by Plans/Part D Sponsors; these are considered non-standardized model materials. Plans/Part D Sponsors that choose to modify the model language must ensure that all content contained in the model is included in the non-model document. Model documents modified by the Plan/Part D Sponsor are subject to a forty-five (45) day review period. Plans/Part D Sponsors are required to include the disclaimers from section 50 in their modified model documents. 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/Part D Sponsor used CMS model language verbatim except where indicated and allowed by CMS, (e.g., variable fields). To facilitate review, Plans/Part D 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, address, date, or enrollee ID,
- Correcting grammatical errors,
- Changing the font,

- Adding any applicable disclaimers,
- Adding the customer service phone number and/or hours of operation 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/Part D Sponsors 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 Plans/Part D Sponsors and cannot be modified in any way.

90.7.2 - Required Use of Standardized Materials

42 CFR 422.2262(c), 423.2262(c)

Standardized materials are documents that a Plan/Part D Sponsor must use without changing the content, format, or order. CMS allows Plans/Part D Sponsors to make the following changes to standardized materials:

- 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 a marketing material that includes placeholders for variable data to be populated at a later time by the Plan/Part D Sponsor. CMS classifies template materials as either static templates or standard templates.

When submitting **unpopulated** templates, Plans/Part D 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>”).

Changes to previously approved non-variable text in a template must be submitted for review and approval by CMS. If there are changes or corrections to final materials (e.g., the benefit or cost-sharing information differs from that in the approved bid), the Plan/Part D Sponsor **must** correct those materials for prospective enrollees and send errata sheets/addenda/reprints to current enrollees by a reasonable timeframe. In cases of non-compliance, the Plan/Part D 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 - Static Templates

42 CFR 422.2262, 423.2262

A **template material is considered a static template when it** includes placeholders for **the following** variable data fields **ONLY**:

- Dates;
- Events;
- Addresses, phone or fax numbers;
- Hours of operation;
- Organization or company names;
- Plan/Part D Sponsor name;
- Logos;
- Agent/Agency;

- Federal contracting statement/disclaimer;
- Persons' names and pronoun variations;
- URLs;
- Enrollee specific variables, (e.g., case numbers, drug specific references);
- Co-branding information;
- Photos;
- Email addresses and web addresses;
- LIS Rider;
- OEV Scripts and Letters; and
- Page number references.

Plans/Part D Sponsors are not required to submit populated static templates in HPMS.

To be considered a static template, ALL variable data fields within the material must be **among those listed above**. Since static templates are not resubmitted, Plans/Part D Sponsors are not required to indicate that the submission is a template when submitting the material in HPMS.

90.8.2 - Standard Templates

42 CFR 422.2262, 423.2262

Standard templates are marketing materials that include placeholders for variable data not listed in 90.8.1, such as plan specific benefits, premiums, and cost sharing. Within thirty (30) days of use, Plans/Part D Sponsors must submit final, populated versions of standard templates in the HPMS Marketing Module using the associated "Final Expedited Review" code. If there is no accompanying "Final Expedited Review" code, Plans/Part D Sponsors may not submit the document as a standard template, but instead must submit the document with all fields populated. Refer to the HPMS Users' Guide for technical template submission instructions.

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 by CMS, Plans/Part D Sponsors may be required to remedy the error by providing beneficiaries with updated information via errata sheets or addenda.**

When errors are discovered by a Plan/Part D Sponsor, the Plan/Part D Sponsor must report the errors to its Account Manager. In addition, Plans/Part D 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 422.504(f)(2), 422.2268, 423.2268, 423.505(f)

CMS periodically conducts reviews of Plan/Part D 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

100 - Plan/Part D Sponsor Websites and Social/Electronic Media

42 CFR 422.111(h), 422.2264, 422.2268, 423.128(d), 423.2264, 423.2268

Plans/Part D Sponsors **must** maintain their current contract year website for **current** beneficiaries through December 31 of each year. They are expected not to include content on their website or on social/electronic media (e.g., Facebook, Twitter, YouTube, LinkedIn, Scan Code, or QR Code) for the next contract year prior to October 1.

All Plan/Part D Sponsor websites must be clear and easy to navigate. Any marketing materials that include a web address for the Plan's/Part D Sponsor's website are expected to link directly to the organization's Medicare-specific pages.

Plans/Part D Sponsors are expected to 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.

Plans/Part D Sponsors should not provide links to foreign drug sales. This includes links from advertisements that may appear on the website.

If a Plan/Part D Sponsor posts **required** information (see sections [100.1](#) and [100.2](#)) to a social media site, **that information must** also be posted on the Plan's/Part D Sponsor's official website **to comply with the disclosure requirement**. For example, enrollees of the public should be able to learn about the requirements in those sections without having to join a third-party social media website.

Events held through social media must adhere to the guidelines set forth in section 70.9.

100.1 - General Website Requirements

All Plan/Part D Sponsor websites are expected to:

- Maintain a separate and distinct section of their website for Medicare information if the Plan/Part D Sponsor markets other lines of business
- 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 a portion of the Plan's/Part D Sponsor's website is disapproved, the disapproved portion must be removed from the website immediately
- 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/Part D Sponsor is expected to post the actual material, rather than duplicating the material's content on the website. These materials must also retain their original Material ID
- **Provide a direct link to the Medicare.gov website where a beneficiary can enter a complaint in lieu of calling 1-800-Medicare**
- **Provide instructions on how to appoint a representative and link to the CMS Appointment of Representative Form (CMS Form-1696)**

All Plan/Part D Sponsor websites must:

- Notify individuals that s/he will leave the Plan's/Part D Sponsor's Medicare information if there is a link on the Plan's/Part D Sponsor's website that will take an individual to non-Medicare information or to a different website
- Post all required translated materials identified in sections 30.6, 30.7, and 30.10 and the Part D transition letter(s), except in cases in which the translated documents will be sent to specific enrollees (e.g., the LIS Rider) if Plans/Part D Sponsors have service areas that meet the 5% language threshold

100.2 - Required Content

All Plans/Part D Sponsors **should review** website content monthly and update as necessary. **Websites** must include:

- Information on beneficiaries' and Plans'/Part D Sponsors' 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, an organization/coverage determination, and an appeal. This information must include:
 - Procedures for filing an organization/coverage determination, a grievance, and an appeal
 - 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/Part D Sponsor for appeals and grievances
 - Information on how to obtain an aggregate number of grievances, appeals, and exceptions filed with the Plan/Part D Sponsor

- Contact numbers that enrollees and/or physicians can use for process or status questions

Part D sponsor website content must include:

- Immediate access to the coverage determination and redetermination processes through a secure location prominently displayed on the website
- Direct links to the Request for Medicare Prescription Drug Determination Request Form(s) for enrollees and providers; the model for the form(s) is 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
- Part D sponsors are expected to include a separate section or page about MTM programs, written in plain language appropriate for beneficiaries, including:
 - Part D Sponsors' specific eligibility requirements,
 - A statement informing beneficiaries about who to contact at the Part D Sponsor for more information, with customer service personnel prepared to answer questions about the MTM program,
 - High level summary of services offered as part of the MTM program,
 - A statement explaining the purpose and benefits of MTM, and that this is a free service for eligible beneficiaries,
 - A description of how the beneficiary will be notified by the Part D Sponsor that they are eligible and enrolled in the MTM program,
 - Statements on how they will be contacted and offered services by the Part D Sponsor, including the comprehensive medication review and targeted medication reviews, and a description of how the reviews are conducted and delivered, including time commitments and materials beneficiaries will receive,
 - A statement on how the beneficiary may obtain MTM service documents, including a blank copy of the Personal Medication List posted on the website, and
 - A statement clarifying that these programs are not considered a benefit.

- The materials in Section [100.2.2](#).

PFFS Plan websites must include:

- A link to Plan's/Part D 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 Plans/Part D Sponsors

All Plans/Part D Sponsors must post the following materials **on the Plan's/Part D Sponsor's website**:

- Summary of Benefits
- Multi-language Insert
- **Annual Notice of Change**/Evidence of Coverage (most current version)
- Provider and/or Pharmacy Directory as applicable
- Privacy Notice under the HIPAA Privacy Rule (privacy notices are subject to enforcement by the Office for Civil Rights)
- CMS Star Ratings document
- Any form developed to be used by physicians when providing a supporting statement for an exceptions request
- Any form developed by the Plan/Part D Sponsor to be used by a physician or enrollee to satisfy a prior authorization or other utilization management requirement

- CMS Part D Model Coverage Determination and Redetermination Request Forms

All Plans/Part D Sponsors must provide the following materials upon request and CMS expects Plans/Part D Sponsors to post them on the Plan/Part D Sponsor website:

- Enrollment Instructions and Forms
- Any form developed by the Plan/Part D 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 Sponsors must post the following materials online:

- Current Comprehensive Formulary (updated at least monthly if changes are made to the formulary), including when applicable:
 - Prior authorization criteria
 - Step therapy criteria
- LIS Premium Summary Chart

Part D Sponsors are expected to post the Prescription Drug Transition Policy online.

100.3 - Electronic Enrollment

Except as described below, all Plans/Part D Sponsors must accept enrollment **requests submitted** through the **Medicare** Online Enrollment Center (OEC).

- **The OEC is not available to individuals seeking enrollment in Medicare Savings Account (MSA) plans and 800 series employer group waiver plans**
- SNPs and Religious Fraternal Benefit plans may, but are not required to, accept enrollment **requests** through the OEC
- Section 1876 cost plans may, but are not required to, accept enrollment **requests** through the OEC

Plans/Part D Sponsors may develop and offer **electronic enrollment mechanisms that permit enrollment requests to be submitted via a Plan/Part D Sponsor-owned electronic device or the Plan's/Part D Sponsor's secure internet website.** (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 electronic enrollment website requirements).

Plans/Part D Sponsors using enrollment software on **Plan/Part D Sponsor-owned** mobile devices (e.g., smartphones or tablets) must submit the mobile pages following the website submission guidance (see [90.2.2](#)).

Enrollment via **a website other than a website owned by the Plan/Part D Sponsor, such as an agent/broker or other third party,** website is not permitted.

100.4 – Online Provider Directory Requirements

MA, MA-PD, and section 1876 cost plans must post a provider directory **that should be printable** 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/Part D Sponsor
- Posting individual provider directories by product and/or service area (e.g., mirroring those that will be printed for the Plan’s/Part D Sponsor’s membership)
- Using a search engine. If a Plan/Part D Sponsor uses a search engine on its website, it must include all the requirements in the model Directory

100.5 – Online Formulary, Utilization Management (UM), and Notice Requirements

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

The requirements in this section apply to online versions of formularies, including UM documents, and notice in Part D Plans and MA-PD Plans.

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 website formulary is expected to meet all of the requirements listed below. Utilization management documents are expected to, at a minimum, fulfill the requirements listed in the first four bullets as well as any other applicable requirements listed below.

- Be available at the start of each new contract year enrollment period
- Be updated at least once per month

- Be available through a link to a downloadable document. In addition, Part D sponsors may provide an on-line formulary search tool but such tools cannot be used as a substitute for the required downloadable documents.
- Indicate when the document and search tool (if available) was last updated by including the phrase, "Updated MM/YYYY" or "No changes made since MM/YYYY"; explain that enrollees can contact the sponsor for the most recent list of drugs; and provide the sponsor phone number, hours, and web address
- Define a comprehensive formulary (either in a link or through an introductory screen)
- Provide an explanation of how to use the search tool, if available
- Be accessible by a drug name search
- Expected to explain or link to an explanation of how to obtain an exception to the Part D sponsor's formulary, utilization management tools, or (if applicable) tiered cost sharing provided when search results indicate a drug is not covered
- Part D Sponsors may include formulary and non-formulary alternatives; however, the formulary alternatives are expected to be clearly marked as formulary drugs without the need for further navigation. If not all formulary alternatives will be listed, the Part D Sponsor is expected to include the following disclaimer: "This is not a complete list of all formulary alternatives covered by the Part D sponsor for the drug you have selected."

Each search result that appears in the downloadable format or search tool is expected to **at a minimum:**

- 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 is expected to be displayed. If prior authorization or step therapy restrictions are applicable, then the criteria is expected to also be included.
- For drugs with a Part B versus D administrative prior authorization requirement, the following statement: "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."

- When the online formulary search tool results indicate a drug is not covered, explain or link to an explanation of how to obtain an exception to the Part D sponsor's formulary, utilization management tools or tiered cost sharing both **by** an introductory screen and when search results indicate a drug is not covered
- Provide 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)

Utilization management documents (detailing the criteria needed to satisfy the prior authorization and/or step therapy requirements) and the transition policy document are reviewed and approved as part of the HPMS formulary review process and not the HPMS marketing process See the Prescription Drug Manual, Chapter 6, section 30.2.7 (<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html>).

Online notices: Part D sponsors **may post** online the notice **of formulary changes**, provided that this notice:

- **Includes notice for all changes** associated with removing or changing a Part D drug **or** adding authorization, quantity limits, step therapy, changing the cost sharing status, or any other restrictions on a drug
- Meets all requirements for written notice specified in the Prescription Drug Manual, Chapter 6, section 30.3.4 (<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html>), which includes **provision of effective date**, name of drug, nature of the change (removed or changed drug to preferred or cost-sharing status), reason for the change, list of alternative drugs and expected cost-sharing, and information on obtaining coverage determination or exception thereto

This information must be maintained on the website until the next annual mailing of the updated formulary.

Electronic notice cannot substitute for notice otherwise required to appear for instance, in the EOB or in writing as specified in the PDM, Chapter 6, section 30.3.4 cited above.

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 engaging marketing representatives to sell Medicare products, Plans/Part D Sponsors must comply with applicable State licensure and/or appointment laws.

120.2 - Plan Reporting of Terminated Agents

42 CFR 422.2272(c)-(e); 423.2272(c)-(e)

Plans/Part D Sponsors must report the termination of any **agents/brokers to the State and CMS**, and the reasons for the termination, **if State law requires the reasons to be reported**.

Upon discovering incidents of unlicensed agents or brokers submitting enrollment applications, **Plans/Part D Sponsors** must terminate the relationship and report the agent/broker to the authority in the State where the application was submitted. Additionally, Plans/Part D Sponsors must notify any beneficiaries **who** were enrolled by unqualified agents/brokers (e.g., unlicensed, not appointed, or has not completed the annual training/testing) and advise those beneficiaries of the agents'/brokers' status. Beneficiaries may request to make a plan change under 42 CFR 422.62(b)(3) or 423.38(c)(8)(i).

120.3 - Agent/Broker Training and Testing

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

Plans/Part D Sponsors must ensure that all agents/**brokers** (employed/**captive** or independent) selling Medicare products are trained and tested annually on Medicare rules, regulations, and on details specific to the plan products that they sell. **This means that training and testing must take place prior to the broker/agent selling the product. In addition, agents/brokers must obtain a passing score of at least eighty-five percent on the test.**

CMS will provide guidance, updated annually, for agents/brokers training/testing. Plans/Part D Sponsors must ensure that their **agents/brokers** training/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 - Compensation Applicability and Definitions

42 CFR 422.2274(a), 423.2274(a)

NOTE: In accordance with CMS-4159-F published on May 23, 2014, section 120.4 provisions will apply on January 1, 2015.

All compensation requirements contained in this section apply to independent agents/brokers. Employed and captive agents/brokers who only sell for one Plan/Part D Sponsor are exempt from compensation requirements, except where noted (e.g., referral/finder fees). However, all other marketing and sales requirements must be met.

Compensation:

Compensation includes monetary or non-monetary remuneration of any kind relating to the sale or renewal of a policy including, but not limited to, commissions, bonuses, gifts, prizes, awards, and referral/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

Initial Compensation:

Initial compensation is paid at or below the fair market value (FMV) cut-off amounts published by CMS annually.

Renewal Compensation:

Renewal compensation is paid for each enrollment in Year 2 and beyond up to fifty (50) percent of the current FMV, published by CMS annually.

A "like plan type" enrollment includes:

- A PDP to another PDP
- An MA, MA-PD, or MMP to another MA, MA-PD or MMP
- 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).

120.4.1 - General Rules Regarding Compensation

Plans/Part D Sponsors may not pay agents/brokers who have not been trained and tested.

Plans/Part D Sponsors may not pay compensation to agents/brokers not meeting licensure/appointment requirements or those that have been terminated for cause.

When a Plan/Part D Sponsor and/or a contracted independent agent/broker terminates the contract, any future payment of existing business will be governed by the terms of the contract.

120.4.2 – Compensation Payment Requirements

42 CFR 422.2274(a), 423.2274(a)

- Plans/Part D sponsors must notify CMS of their compensation schedule in HPMS by the date specified each year
- Plans/Part D sponsors may decide each year whether or not they will use independent agents
- The compensation year is January 1 through December 31 of each year. Payments must be calculated based on the January through December enrollment year. Payments may not be based on enrollment years (rolling basis) other than January through December. 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 **who** assisted this beneficiary.

- Initial compensation is paid for the beneficiary's first year of enrollment
- Initial compensation is also paid when a beneficiary enrolls in an "unlike plan type," if the beneficiary is currently in a renewal year
- Renewal compensation is paid following the initial year compensation
- Renewal compensation is also paid when a beneficiary enrolls in a new, "like plan type." A new "like plan type" may be a change from one plan to another plan within the same Parent Organization or between different Parent Organizations.
- The monthly MARx agent/broker compensation report will provide Plans/Part D Sponsors with the information necessary to determine whether they should make an initial or renewal payment
- Compensation may only be paid for the number of months a beneficiary is enrolled
- Plans/Part D Sponsors may only pay compensation for the current year enrollment. Payments may not be paid until January 1 and must be paid in full by December 31 of the enrollment year. Plans/Part D Sponsors may pay compensation annually, quarterly, monthly, or utilizing other schedules.
- When a beneficiary enrolls in a plan and has no prior plan history (as indicated on the MARX agent/broker compensation report), Plans/Part D Sponsors may pay the full year initial compensation amount or a pro-rated amount based on the number of months the beneficiary is enrolled
- When a beneficiary changes plans during the initial year, the Plan/Part D Sponsor must pay the agent/broker at a pro-rated initial year rate, based on the number of months the beneficiary is enrolled. For example, if an initial beneficiary changes from one Parent Organization to another Parent Organization in May, the new Parent Organization must pay 8/12ths of the initial compensation.
- The movement by a beneficiary from an employer group plan to an individual plan (either within the same Plan/Part D Sponsor or between different Plan/Part D Sponsors) counts as an initial enrollment

- When a beneficiary enrolls in an MA-PD plan, compensation should be paid using the MA compensation amount. MA-PD Plans should not pay both the MA and PDP compensation amounts.
- 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)
- If the Plan/Part D Sponsor **contracts with a third party entity to sell its products**, the Plan/Part D Sponsor **must ensure payment is at or below the initial and renewal compensation maximum amounts**
- Plans/Part D Sponsors must establish a compensation structure for new and replacement enrollments and renewals effective in a given plan year that must be available upon CMS request for audits, investigations, and to resolve complaints. Compensation structures must be in place by the beginning of Annual Enrollment Period (AEP), which is October 1.
- Compensation for referral/finder's fees paid to all agents and brokers, which includes independent, employed, and captive agents and brokers, may not exceed \$100 for an agent or broker to recommend or enroll a beneficiary into a Plan/Part D Sponsor that meets beneficiaries' healthcare needs.
- Referral/finder's fees paid to all agents and brokers must be part of total compensation not to exceed FMV for that contract year.

120.4.3 - Compensation **Recovery Requirements** (Charge-backs)

42 CFR 422.2274(a)(4)(ii), 423.2274(a)(4)(ii)

Plans/**Part D Sponsors must** recover compensation payments from agents/**brokers** 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.

Rapid Disenrollment

- **Rapid disenrollment applies when an enrollee moves from one Parent Organization to another Parent Organization, or when a enrollee moves from one plan to another plan within the same Parent Organization**
- **Rapid disenrollment compensation recovery does not apply when a beneficiary enrolls in a plan effective October 1, November 1, or December 1, and subsequently changes plans effective January 1 of the following**

year. If, however, a beneficiary enrolls in October and disenrolls in December, the Plan/Part D Sponsor should **recover compensation based on the** rapid disenrollment.

- **Rapid disenrollment compensation recovery does not apply** when a beneficiary disenrolls within the first three months **for any of the following reasons:**
 - Other creditable coverage
 - **Moving into or out of an institution**
 - Gains/drops employer/union sponsored coverage
 - CMS sanction against the plan/**contract violation**
 - **Plan terminations and non-renewals**
 - In order to coordinate with Part D enrollment periods
 - In order to coordinate with an SPAP
 - 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
 - Due to an auto- or facilitated enrollment
 - Death
 - Moves out of the service area
 - Non-payment of premium
 - Loss of entitlement
 - Retroactive notice of Medicare entitlement
 - When moving to a plan with a 5-star rating or out of a low performing plan.

Other Compensation Recovery

- Plans/Part D Sponsors must recover a pro-rated amount of initial compensation when an enrollee disenrolls from a plan. The amount recovered must be equal to the number of months not enrolled. For example, an enrollee *ages in* effective April 1. The enrollee disenrolls effective September 30 of the same year. The plan initially paid a full initial compensation. Since the enrollee disenrolled (not a rapid disenrollment), the Plan/Part D Sponsor must recover 6/12ths of the initial compensation (January through March and October through December).
- Plans/Part D Sponsors must recover a pro-rated amount of renewal compensation when an enrollee disenrolls from a plan. This amount must be equal to the number of months not enrolled. For example, a renewal enrollee disenrolls effective February 28. The Plan/Part D Sponsor must recover 10/12ths of the renewal payment.

120.4.4 - Payments other than Compensation

42 CFR 422.2274, 423.2274

Payments made to third parties for services other than enrollment of beneficiaries (e.g., training, customer service, or agent recruitment) must not exceed an amount that is commensurate with the amounts paid by the Plan/Part D Sponsor to a third party for similar services during each of the previous two (2) years.

120.5 - Additional Marketing Fees

42 CFR 422.2274(a), 423.2274(a)

A Plan/Part D 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/Part D Sponsor.

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

42 CFR 422.2272(c), 423.2272(c)

The following activities conducted by a plan customer service representative do not require the use of a State-licensed marketing representative because they are not marketing activities. **These include:**

- 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
- “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/Part D Sponsor materials such as enrollment packets

However, if Plans/Part D Sponsors use licensed agents/brokers (employed or contracted) as customer service representatives, they cannot act as both a customer service representative and a sales/marketing agent/broker.

130 - Employer/Union Group Health Plans

Sections 1857(i) and 1860D-22(b) of the Social Security Act, 42 CFR 422.2276, 423.458, 423.2276

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. **Waivers are limited in scope to their stated parameters, and employer group waiver plans (EGWPs) must follow all Part C and D rules unless explicitly waived.** 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 Chapter 9 of the Medicare Managed Care Manual, and Chapter 12 of the Prescription Drug Benefit Manual.

Plans 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 Chapter 9 of the Medicare Managed Care Manual, and Chapter 12 of the Prescription Drug Benefit Manual.

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

| |
|--|
| <p><u>Marketing Provisions that apply to Employer/Union Group Plans</u></p> <p>These requirements are applicable for the transaction between the</p> |
|--|

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.

Note: This table contains a partial list of exclusions. Please refer to Chapter 9 of the Medicare Managed Care Manual, and Chapter 12 of the Prescription Drug Benefit Manual for additional information.

| Provision | Applicable | Non-Applicable (Waived) |
|---|-----------------|-------------------------|
| 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 must comply with all applicable guidance set forth in this chapter. Additionally, MSA plans may not:

- Imply that the plan operates as a supplement to Medicare

- Use the term “network” to describe a list of contracted preferred providers
- See section 100 for additional MSA requirements related to websites.

150 - Use of Medicare Mark for Part D Sponsors

Section 1140 of the Social Security Act

All Part D Sponsors 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 Sponsors are authorized to use the Medicare Prescription Drug Benefit Program Mark only after electronically executing the Medicare Mark License Agreement in HPMS. In certain circumstances, the Medicare Mark License Agreement may be signed in hard copy rather than electronically. Only a CEO, CFO, or COO who is designated as an authorized signer in HPMS is eligible to execute the Medicare Mark License Agreement. Part D Sponsors 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 Sponsors 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 section [70.1.1](#). 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. The Part D Sponsor electronically signs the Medicare Mark License Agreement in HPMS (or signs a hardcopy, as applicable)
2. CMS counter-signs the Part D Sponsor's contract
3. CMS sends the Medicare Mark URL to the Part D 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 the Medicare Prescription Drug Benefit Program Mark

Section 1140 of the Social Security Act

Unless otherwise approved, no individuals, organizations, and/or commercial firms may 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

42 U.S.C. section 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:

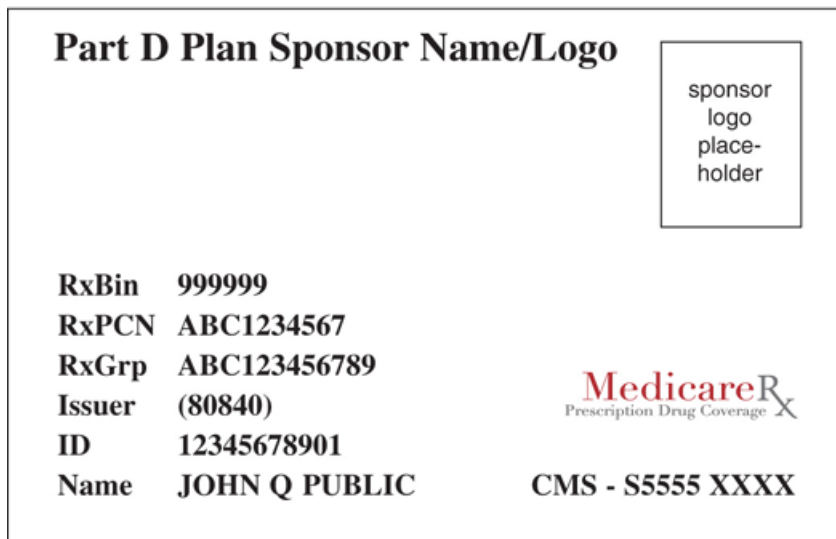
- Do not alter the position of the mark elements
- Do not alter the aspect ratio of the certification mark. Do not stretch or distort the mark.
- Always use the mark only as provided in the CMS approval/license agreement
- Do not rotate the mark or any of its elements

- 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 – Mark Guidelines for Part D Standard Pharmacy ID Card Design

Section 1140 of the Social Security Act

Usage of the Medicare Prescription Drug Benefit Program Mark on an ID Card must be consistent with section [60.2](#) of this chapter.



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. Plans/Part D 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 Plans/Part D 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 Data Use Agreement in connection with such data, we encourage Plans/Part D 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/Part D 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 Plans/Part D Sponsors on the distribution of other types of non-plan related information.

160.1 - When Prior Authorization from the Beneficiary Is Not Required

Plan/Part D Sponsor marketing materials describing health-related lines of business to current enrollees do not require prior authorization (See 40.8 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/Part D 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

Plans/Part D 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 section [160.2](#) may be obtained. With any of these examples, Plans/Part D Sponsors must receive the enrollee's "opt-in" authorization prior to sending any non-plan or non-health related information, and Plans/Part D Sponsors should keep evidence of authorization for audit purposes.

- Plans/Part D 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 section 100.1. Once a beneficiary “opts-in,” the Plans/Part D 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 section 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/Part D Sponsor has previously received prior authorization to send that particular non-health related information to that enrollee. 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 enrollees, 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 enrollees 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 section 20, Plans/Part D Sponsors are still responsible for ensuring that all materials intended for Medicare beneficiaries meet the requirements of this chapter and applicable law (e.g., the HIPAA Privacy Rule), **and for maintaining such materials so as to make them available, through HPMS or other means, upon CMS' request.**

CMS is adopting the same requirements for these authorizations as are 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 enrollees 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

422.111, 422.2260, 423.2260, 422.2268, 423.128, 423.2268

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 or cover enrollee-specific claims processing or other operational issues, and which do not include information about the plan's benefit structure. **In addition, these communication materials are those that are not tied to regularly occurring events like people who are aging into Medicare, the Annual Enrollment Period, or a new contract year.** These materials are not considered marketing materials and should be in a clear **and** accurate format. Examples of these materials include, **but are not limited to**, 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 enrollee-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/Part D 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/Part D 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/Part D 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. Co-branding means when the Plan/Part D 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/Part D 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/Part D 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/Part D Sponsor, or any MA plan, MA-PD plan, section 1876 cost plan, or PDP offered by the Plan/Part D 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/Part D 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/Part D Sponsor may promote specific benefits/premiums and/or services offered by the plan. Plans/Part D Sponsors may conduct a formal event where a presentation is provided to Medicare beneficiaries or an informal event where Plans/Part D Sponsors are only distributing health plan brochures and pre-enrollment materials. Plans/Part D 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.

Medication Therapy Management (MTM) program materials are:

- Materials provided to enrollees enrolled in the MA or PDP plan who are eligible for the plan's MTM program;

- Materials that address issues unique to individual enrollees; and
- The Part D MTM program comprehensive medication review summary in CMS' standardized format that is provided to a beneficiary

Note: MTM materials must not include any marketing messages, or promotional messages.

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 Plans/Part D Sponsors that have multiple MA/PDP contracts with CMS. Being designated as an MCE allows a Plan/Part D Sponsor to submit template materials to CMS that are representative of all or a selection of the Plan's/Part D 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/Part D 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/Part D Sponsor, or by an individual or organization on a Plan's/Part D Sponsor's behalf, to inform current and potential enrollees of the products available.

Scripts

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

Standardized Language

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

State Pharmaceutical Assistance Program (SPAP)

An SPAP is a state program which helps pay drug plan premiums and/or other drug costs for people with Medicare.

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's/Part D Sponsor's Medicare products on the Plan's/Part D 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's/Part D Sponsor's enrollees. An item or service is classified as a VAIS if the cost, if any, incurred to the Plan/Part D 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)

Americans with Disabilities Act of 1990

Federal agencies are required to provide notice concerning the need for reasonable accommodation for its beneficiaries, as well as providing those accommodations.

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 Plans, Part D sponsors, and downstream contractors that may be directly or indirectly involved in marketing Medicare plans. Plans/Part D Sponsors should ensure that their subcontractors are not using the Medicare name in a misleading manner.

Privacy and Confidentiality

42 CFR 422.118, 423.136

Plans/Part D Sponsors and providers are responsible for following all Federal and State laws regarding confidentiality and disclosure of patient information to Plans/Part D 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 section [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, 164

Plans/Part D 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’s/Part D

Sponsor's benefits or the Plan's/Part D Sponsor's health-related value-added products and services that are only available to plan enrollees, but are not part of the enrollee's plan of benefits. These categories are explicitly noted as exceptions to the definition of marketing in the HIPAA Privacy Rule. See, 45 FR 5566 at 5592. In complying with these exceptions, Plans/Part D Sponsors may be able to use and disclose protected health information to make communications to enrollees about other health-related lines offered provided by the covered entity.

However, Plans/Part D Sponsors must obtain written authorization from an enrollee prior to using or disclosing the enrollee's protected health information for any communications that encourage the recipients to buy or use a product or service that does not fall within the exceptions to the definition of marketing under the HIPAA Privacy Rule. For example, enrollee authorization is likely 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, section 503(b), Departments of Labor, HHS, and Education Appropriations Act, 2009, as enacted by section 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 Plans/Part D 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 Plans/Part D Sponsors through the requirements for non-discrimination under Federal grants and programs (29 USC section 794).

Section 504 of the Rehabilitation Act

All Plans/Part D Sponsors are required to ensure effective communication with individuals with disabilities and to provide auxiliary aids and services, such as alternate formats, to individuals with disabilities to ensure effective communication and an equal opportunity to access the agencies' programs. These and other prohibitions against discrimination based on disability can be found in the DHHS Section 504 regulation at 45 CFR Part 84.

Mailing Standards

Plans/Part D Sponsors must comply with the mailing standards of the United States Postal Service contained in the Domestic Mail Manual.

Plain Writing Act of 2010

(P.L. 111-274, 124 STAT. 2861 (October 13, 2010))

Plans/Part D Sponsors are required to write all Medicare publications, forms, and publicly distributed documents in a clear, concise, and well-organized manner.

Appendix 3 – 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: 我們提供免費的翻譯服務，幫助您解答關於健康或藥物保險的任何疑問。如果您需要此翻譯服務，請致電 1-xxx-xxx-xxxx。我們的中文工作人員很樂意幫助您。這是一項免費服務。

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 panggamot. 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:

إننا نقدم خدمات المترجم الفوري المجانية للإجابة عن أي أسئلة تتعلق بالصحة أو جدول الأدوية لدينا. للحصول على مترجم فوري، ليس عليك سوى الاتصال بنا على [1-xxx-xxx-xxxx]. سيقوم شخص ما يتحدث بمساعدتك. هذه خدمة مجانية العربية.

Hindi¹

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.

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

Pharmacy Technical Help Call Center Requirements

42 CFR 423.128(d)(1)

Part D Sponsors 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 usual business hours, which CMS interprets to mean** during the entire period in which the Part D Sponsor's network pharmacies in its plans' service areas are open (e.g., Part D 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).

To be considered fully compliant with the regulatory requirement to meet standard customer service business practices, the pharmacy technical help call center operates within the following 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

Part D Sponsor Coverage Determinations and Appeals Call Center Requirements

423.128(b)(7), 423.128(d)(1)(iv), 423.566(a)

All Part D Sponsors 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), **and** appeals. Part D 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, **which CMS interprets to mean at least** from 8:00 a.m. to 8:00 p.m., Monday

through Friday; in the time zones for the regions in which they operate. Part D 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 and the voice mail message should:

- Indicate that the mailbox is secure
- List 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 enrollee is making an expedited or standard request)
- For coverage determination calls (including exceptions requests), articulate and follow 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