Medicare Marketing Guidelines

For Medicare Advantage Plans[1], Medicare Advantage Prescription Drug Plans, Prescription Drug Plans, Employer/Union-Sponsored Group Health Plans, Medicare-Medicaid Plans, and Section 1876 Cost Plans

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[1] *While Medicare Advantage "plans" are specific benefit packages offered by a Medicare Advantage "organization," in this chapter, "plan" is used both to refer to the MA plan and to the MA organization offering the plan.*

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, MA-PD) (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 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://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/InformationandGuidanceforPlans.html as it is finalized. These requirements do not apply to Program of All-Inclusive Care for the Elderly (PACE) plans or section 1833 Health Care Pre-payment Plans unless otherwise noted in the MMG.

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 of "marketing materials" 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, may fall under CMS' purview per the definition of marketing materials:

- 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., Annual Notice of change (ANOC), Evidence of Coverage (EOC), Provider/Pharmacy Directory)

- Communications to enrollees about contractual changes, and changes in providers, premiums, benefits, plan procedures

- Membership activities (e.g., materials on 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 contribute 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. 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.

- 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 marketing requirements described in the MMG

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 types of materials are not subject to CMS marketing review, should not be submitted in HPMS, and do not require a material ID number. However, Plans/Part D Sponsors are still responsible for maintaining such materials and must make them available, through HPMS or other means, upon 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)
- Enrollee newsletters 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)
- Blank letterhead/fax coversheets/blank pages 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 section 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 (refer to Chapter 4 of the Medicare Managed Care Manual) See definition in Appendix 1
- Documents encouraging enrollees to use preventive services
- Mid-year Change Enrollee Notifications (Refer to 60.8)
- Informational Scripts
- Marketing materials created by State government
- Password protected websites that only currently enrolled members can access

  Note: Marketing materials included on the website are still subject to review (e.g., Plan/Part D Sponsor advertisements).

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)

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

A Plan/Part D Sponsor is prohibited from advertising outside of its defined service area unless unavoidable. For unavoidable situations, (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 must 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.

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 bid user's manual 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(i), 423.505(i), 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 guidance, 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: The following types of materials do not need to be submitted into HPMS:

- Business cards that do not mention plan specific benefits
- Materials, except for websites, that only indicate the products (e.g., HMO, PPO, or PDP) an agent sells. Plans/Part D Sponsors must submit agent/broker websites that reference specific MA/Part D products in HPMS.

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/ imply that plans are only available to seniors rather than to all Medicare beneficiaries. Only Special Needs Plans (SNPs) and MMPs may limit enrollments to individuals meeting eligibility requirements based on health and/or other status. 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), 422.112(a)(8), 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, 30.9, 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 submitted in 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) and (e), 423.128(d) 423.2262(c), 423.2264(a) and (e)

The Multi-Language Insert is a document stating, "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." CMS currently has

the following languages included on the multi-language insert: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese. If the 5 percent service area threshold (See 30.5) is applicable to a language not currently on the Multi-Language Insert, the Plan/Part D Sponsor must add the statement above in that particular language.

Regardless of the five (5) percent service area threshold (see section 30.5), all Plans/Part D Sponsors must include the CMS Multi-Language Insert with the Summary of Benefits (SB), Annual Notice of Change (ANOC)/Evidence of Coverage (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.

The Multi-Language Insert cannot be modified except to include additional languages and/or to insert the Plan/Part D Sponsor logo/name.

> Note: Dual SNPs (D-SNPs) that contract 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

The following materials are required to be included with an enrollment form:

- Star Ratings document (as specified in section 30.9),
- Summary of Benefits,
- Multi-Language Insert (see section 30.5.1)

Note: For online enrollment requests, the Plan/Part D Sponsor 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)

Plans/Part D Sponsors are required to provide the following materials for new and renewing enrollees at the time of enrollment. The materials are required annually thereafter except where noted.

- ANOC/EOC or EOC, as applicable (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 for delivery (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)

- A hard copy pharmacy directory, or separate notice to alert enrollees where they can find the pharmacy directory online and how they can request a hard copy (Part D Sponsors only; see sections 60.4 and 60.4.1 for additional information)

- A hard copy provider directory, or separate notice to alert enrollees where they can find the provider directory online and how they can request a hard copy (For all plan types except PDPs; see sections 60.4 and 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 section 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 – 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 sections 70.1.1, 70.2, and 70.3 for additional guidance on limits for gifts provided to enrollees or prospective enrollees)

30.9 – 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 when the SB and/or the enrollment form is provided to beneficiaries. The Star Ratings information document must also be prominently posted on plan websites.

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. 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 and must also post the Star Ratings information document prominently on their plan websites.

To create the Star Ratings information 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 through instructions.

30.9.1 – Referencing Star Ratings in Marketing Materials

42 CFR 422.2262, 422.2264, 422.2268(e), 423.2262, 423.2264, 423.2268(e)

Plans/Part D Sponsors may only reference a contract's individual measures in conjunction with its Overall Rating (for MA-PDs), its Part C summary rating (for MA-only plans), or its Part D summary rating(for PDPs) in marketing materials. Therefore, whenever individual measures are mentioned, the Plan's/Part D Sponsor's overall (summary) rating must be clearly presented with equal prominence. 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 may not use their Star Ratings in a manner that misleads 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 and Activities*

  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.

30.9.2 – Plans with an Overall 5-Star Rating

42 CFR 422.2262, 422.2264, 422.2268(e), 423.2262, 423.2264, 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 may not specifically target beneficiaries enrolled in poor performing plans or direct beneficiaries 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 each Fall.

Plans/Part D Sponsors with an overall 5-star rating under a Parent Organization with one or more contracts that do not have an overall 5-star rating must 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.

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.

30.9.3 – Low Performing Plans

42 CFR 422.2262, 422.2264, 422.2268(e), 423.2262, 423.2264, 423.2268(e)

Plans/Part D Sponsors assigned a Low Performing Icon (LPI) 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 three (3) star overall rating but has an LPI because of its low Part C ratings may advertise that its overall Star Rating is three (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 a plan, they can later request an SEP and change to a higher-rated plan.

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, 423.2262, 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) Plan/Part D Sponsor 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. See sections 90.2.1 and 90.3.6 for additional information about the submission of non-English and alternate format materials.

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)(3), 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. If a Plan/Part D Sponsor uses a non-CMS study/survey in its marketing materials, the Plan/Part D Sponsor must include the following information, in text or as a footnote, on marketing pieces:

- Statement that the study/survey or statistical data is not endorsed by Medicare;
- The name of the organization sponsoring the study;
- Information about the Plan's/Part D Sponsor's relationship with the entity that conducted the study; and,
- The publication title, date, and page number.

Note: This information should also be included in the HPMS marketing material transmittal comments field when submitting the document that includes the reference. Marketing reviewers/Account Managers may request additional information about the study/survey.

Additionally, if the marketing piece cites a non-CMS award, Plans/Part D Sponsors must:

- State that the award was not given by Medicare;
- State 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 information relative to other awards or surveys mentioned.

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 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 part of the marketing review process or they are used in logos/taglines. 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.

- Market that they will not disenroll members due to failure to pay premiums.

- 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.

Note: 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.

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 (e.g., Facebook, Twitter, YouTube, LinkedIn, Scan Code, or QR Code) 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 are required to be included when any (current or prospective enrollee) customer service number is provided, excluding ID cards. 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 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
- 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.

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 to prospective enrollees, provided that such materials are in compliance with applicable State law and Federal Medicare regulations.

40.8.1 – Multiple Lines of Business - General Information

42 CFR 422.2268(e) and (f), 423.2268(e) and (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 potentially misleading and 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. After giving consent for electronic mailings, the enrollee must be able to opt out and receive hard copy mailings again upon request.

Plans/Part D Sponsors may provide Provider and/or Pharmacy Directories electronically without prior consent from the enrollee. Please see section 60.4 for additional information.

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

- Provide instructions on how and when the electronic documents may be accessed if they are not sent directly to the enrollee. For example, posting the document on a plan website is not sufficient, even if an enrollee has opted into receiving electronic communications. Plans must also provide an email or hard copy notice informing the enrollee where the document will be posted and when the documents will be available. See section 60.4 for requirements specific to the Provider and Pharmacy Directories.

- Provide hard copies (excluding plan web pages) of all enrollee materials available to enrollees upon request.

- 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 email account).

- Ensure compliance with HIPAA and privacy rules.

40.10 – Standardization of Plan Name Type

42 CFR 422.2268 (q), 423.2268 (q), sections 1851(h)(6) and 1860D-4(l)(3) of the Social Security Act

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

The disclaimers described in this section are required, when applicable, on all marketing materials created by the Plan/Part D Sponsor except those noted below. 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:

- ID cards

- Call Scripts
- Banners and banner-like ads
- Envelopes
- Outdoor advertising
- Social Media

  Note: 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 a [plan type] with a Medicare contract. Enrollment in [Plan's/Part D Sponsor's legal or marketing name] depends on contract renewal."

> Note: In addition to the exceptions noted in the introduction to section 50, radio, television, and internet banner ads do not need to include the Federal contracting disclaimer.

50.2 – Disclaimers When Benefits Are Mentioned

42 CFR 422.111(a) and (b), 422.2264, 423.128(a) and (b), 423.2264

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

- "This information is not a complete description of benefits. Contact the plan for more information."

- "Limitations, copayments, and restrictions may apply."
- "[Benefits, premiums and/or co-payments/co-insurance] may change on January 1 of each year."

Plans/Part D Sponsors may select the options within the brackets that are applicable to the marketing piece. For example, if an advertisement mentions co-payments, but does not mention premiums, the disclaimer does not need to specify that the premium may change January 1.

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."

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 (see 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 version 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. Radio ads are only required to include the disclaimer in the same language as the ad.

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.

- "[Premium, 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/Pharmacies

42 CFR 422.2268(n), 423.2268(n)

Plans/Part D Sponsors that enter into co-branding relationships with network providers/pharmacies 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 422.2268(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 their 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/Provider Directory and Formulary Disclaimers
42 CFR 422.111(a) and (b), 423.128(a) and (b)

The following disclaimer must be included on materials whenever formularies and/or provider/pharmacy networks are mentioned:

- "The [Formulary, pharmacy network, and/or provider network] may change at any time. You will receive notice when necessary."

Plans/Part D Sponsors may include only the relevant elements in the brackets.

The following are expected to be included on Pharmacy/Provider Directories:

- If a directory is for 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 enrollees to call when their mail order drugs do not arrive within the estimated time frames.
- Advise enrollees that they have they have the choice to sign up for automated mail order delivery.

Part D Sponsors with limited access to preferred cost sharing pharmacies must include the following disclaimer on materials that reference preferred cost sharing pharmacy networks and/or preferred cost sharing benefits:

> "<insert organization/plan name>'s pharmacy network offers limited access to pharmacies with preferred cost sharing in <insert geographic area type(s) and state(s) for which plan is an outlier)>. The lower costs advertised in our plan materials for these pharmacies may not be available at the pharmacy you use. For up-to-date information about our network pharmacies, including pharmacies with preferred cost sharing, please call <insert Member Services phone number and TTY> or consult the online pharmacy directory at <insert website>."

50.16 – Mailing Statements

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

To ensure that beneficiaries can quickly and easily identify the contents of a Plan's/Part D Sponsor's mailing, all mailings to prospective or current Medicare beneficiaries must prominently display one of the following four statements, verbatim, on the front of the envelope. If no envelope is being sent, the disclaimer must be on 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" (see section 160.4 for examples)

Plans/Part D Sponsors must use these statements.

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.

50.17 – Disclaimer for Other Formulary Documents

42 CFR 423.128(a) and (b)

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 section 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 sections 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's/Part D Sponsor's website address
- The Plan's/Part D Sponsor's customer service number
- The CMS contract number/PBP number

Plans/Part D Sponsors may not use the social security number (SSN) or Healthcare Insurance Claim Number (HICN) as the enrollee identification number on the 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))

(See 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.

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

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 (see 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.).

Informational materials that are enclosed with the post-enrollment mailing must be:

- Distinct (e.g., folded, different color pages, tabbed) from the required document within the mailing envelope. All documents must be distinct if binding additional materials with required documents.

- These materials must comply with all relevant laws and regulations, and may not include materials advertising additional products such as Medigap by the Plan/Part D Sponsor.

Note: Materials, other than those described in this section, may not be included in the ANOC/EOC mailing unless otherwise specified (e.g., ANOC/EOC instructions).

60.4 – Directories

42 CFR 422.111(a) and (b)(3)(i), 422.111(e), 422.111(f),422.111(h), 423.128(a) and (b)(5), 423.128(d), 422.2260, 423.2260, 422.2262(c), 423.2262(c)

Under the regulations cited above, Plan/Part D Sponsors have flexibility in providing access to their provider/pharmacy directories. At the time of enrollment, and at least annually after that by September 30, Plans/Part D Sponsors must send all enrollees either the Provider/Pharmacy Directory (as applicable) in hard copy or a distinct and separate notice (in hard copy), describing where the enrollee can find the provider/pharmacy directories online and how the enrollee can request a hard copy. This notice must be a standalone document (i.e., not bound with other materials) and may be included in the same mailing as the ANOC/EOC.

For Plans/Part D Sponsors that send a notice, the following rules apply:

- The notice must include the following language: "If you want a Provider/Pharmacy Directory [as applicable] mailed to you, or if you need help finding a network provider and/or pharmacy, please call [customer service phone #]. You may also email your request for the directory at [Plan/Part D Sponsor email address]. You can always access our online [searchable, if applicable] directory at [URL]."

- This notice is subject to the translation requirement in section 30.5.

Plans/Part D Sponsors must ensure that the Plan's/Part D Sponsor's website contain current directories at all times. Plans/Part D Sponsors must also provide the option on their websites for users to request a hard copy provider/pharmacy (as applicable) directory. Plans/Part D Sponsors are expected to mail the requested directory within three (3) business days of the request.

See section 100 for additional website requirements.

MA-PD plans and section 1876 cost plans that offer prescription drug coverage may combine the model provider and model pharmacy directories in one document; this is not considered a modification to the model as long as no other changes are made.

MA, MA-PD, 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 separate 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 the 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 the enrollee with 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. (For more details, see Chapter 4, Section 110.1.2 – Significant

Changes to Networks of the Medicare Managed Care Manual, titled "Benefits and Beneficiary Protections").

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

- 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;
- Customer service number(s) where answers to questions about the network changes will be available; and
- Language on notices to enrollees who will be affected by a provider termination: "If you want a Provider/Pharmacy Directory mailed to you or if you need help finding a network provider/pharmacy, please call [phone #]. You may also email your request for the directory at [email address]. You can always access our online [searchable, if applicable] directory at [URL]."

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 there will be significant changes to the provider/pharmacy and/or facility network, the organization should work with CMS through their Account Manager to create a special mailing to be sent to enrollees.

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 enrollees 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 sponsors 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.

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 available, online and hard copy, 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 an abridged formulary document that includes at a minimum:

- Sponsor 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
- The date the formulary was last updated and describe how to obtain updated formulary information
- 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 enrollees. 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 enrollee 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)
  - 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 enrollees 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 Enrollees 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 enrollees 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. A sixty (60) day notice must be provided in writing unless a beneficiary has affirmatively elected to receive electronic notice. Part D Sponsors should refer to Chapter 6 of the Prescription Drug Manual, section 30.3.4.1 (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html).

If a Part D Sponsor does not provide 60 days advance written notice to an affected enrollee, the Part D Sponsor must provide a 60-day fill of the prescription under the same terms as previously allowed, with written notice of the change.

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 (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.

MMPs that use the Part D EOB model are expected to include all Medicaid-required excluded drugs/OTCs, which are submitted on the Additional Demonstration Drug (ADD) file. For more information, please refer to the Part D EOB Model instructions.

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 sponsor'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. 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 and the number of enrollees that were mailed the documents 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 mail date for each wave. Organizations may enter up to ten waves of mailings. 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) and (e), 423.128(g)

CMS requires enrollee notification of mid-year benefit changes at least 30 days prior to the effective date. Examples of changes include National Coverage Determination (NCD) changes, plan rule changes, or provider network changes. In many cases, Plans/Part D Sponsors may use a variety of mechanisms to inform enrollees of these changes in coverage.

For NCD changes, if Plans/Part D Sponsors choose to provide notification via Plan/Part D Sponsor website, Plans/Part D Sponsors must publish the notification in the next plan newsletter or other mass mailing not specifically dedicated to the NCD notification. Alternatively, Plans may 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.

Plans/Part D Sponsors should refer to the appropriate guidance for the requirements of each change. For more information visit:

- NCD http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?list_type=nca
- Part D Manual http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html.

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;

- Be offered to all people regardless of enrollment and without discrimination;

- Not be items that are considered a health benefit (e.g., a free checkup); and

- 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), (b), and (c), 423.2268(a), (b), and (c)

Plans/Part D Sponsors may offer gifts to potential enrollees, as long as those gifts are of nominal value, provided regardless of enrollment, and without discrimination.

The following rules must be followed when providing nominal gifts:

- If a nominal gift is one large gift (e.g., a concert, raffle, drawing), the total fair market value must not exceed the nominal per person value based on attendance. For example, if 10 people are expected to attend an event, the nominal gift may not be worth more than $150 ($15 for each of the 10 anticipated attendees). 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 gifts and gift cards.

70.2 – Marketing of Rewards and Incentives Programs

42 CFR 422.134, 422.2268

Rewards and incentives programs are for current enrollees only. However, Plans may include information about rewards and incentives programs in marketing materials to potential enrollees, as long as those communications:

- Are provided to all potential enrollees without discrimination;
- Are provided in conjunction with information about Plan benefits; and
- Include information about all rewards and incentives programs offered by the Plan, and are not limited to a specific program, or a specific reward or incentive within a program.

For information regarding rewards and incentives program requirements, please see Chapter 4 of the Medicare Managed Care Manual.

Note: Nominal gifts that are part of a promotional activity are different from rewards and incentives.

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 email lists to distribute information about MA, PDP, or section 1876 cost plans, and may not send electronic communications to individuals at email 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 email or other electronic 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's/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), (e), and (f), 423.2268(d), (e), and (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 a friend or relative. 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 conduct the following telephonic activities:

- Call beneficiaries who submit enrollment applications to conduct quality control and/or agent/broker oversight activities.
- Call their current MA and non-MA enrollees or use third-parties to contact their current MA and non-MA enrollees about 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/MMP plan enrollees to talk about its Medicare products.
- Call their current MA enrollees to promote other Medicare plan types or to discuss plan benefits (e.g., sponsors may contact their PDP

members to promote their MA-PD offerings; Plans/Part D Sponsors that are also Medigap issuers may market their MA, PDP, or cost plan products to their Medigap enrollees).

- Call their current enrollees, including via automated telephone notification, to discuss/inform them about general plan information such as Annual Enrollment Period (AEP) dates, availability of flu shots, upcoming plan changes, educational events and other important plan information.

- 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 conducted telephonically or mailed. Surveys conducted in either manner may not include sales or marketing information.

- Under limited circumstances and subject to advance approval from the appropriate CMS Account Manager, 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 from individuals or enrollees, as these are not considered unsolicited contacts.

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 agent/broker assisted 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 the enrollment verification process into an existing practice, such as Welcome Calls, without making a separate call for enrollment verification. If the Plan/Part D Sponsor chooses to utilize a telephonic contact but is unable to speak with the individual or his or her appointed/authorized representative directly, the Plan/Part D Sponsor 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/Part D Sponsor 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 the plan works (e.g., HMO, PFFS, Section 1876 Cost plan)
- 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's/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 last calendar day of the month prior to 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 should not delay the processing of 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 verification contacts should be made to the applicant only after the enrollment request is received. 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 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(l), 423.2268(l)

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 including the distribution of marketing materials or the distribution/collection of plan applications. This includes the distribution of any material with plan-specific information (including plan-specific premiums, co-payments, or contact information). 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 informing beneficiaries about their products; rather, it is to ensure that events that are advertised as "educational" are only educational and 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.

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.
- Responding 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(l), 423.2268(l)

Plans/Part D Sponsors that hold enrollee-only educational events may not conduct enrollment or sales activities, as described in section 70.8, during these events. Plans/Part D Sponsors may discuss plan-specific premiums and/or benefits and distribute plan-specific materials to enrollees. In this context only (i.e., events for existing enrollees only), this discussion of benefits is not considered a sales activity.

Educational events must be explicitly advertised as "educational;" otherwise, they will be considered by CMS as sales/marketing events. 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) with a sales person or 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/Part D Sponsors 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)

All Plan/Part D Sponsor one-on-one appointments with beneficiaries, regardless of the venue (e.g., in home, conference call, library), are considered sales/marketing events and must follow the scope of appointment guidance (see section 70.9.3).

Note: 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 48 hours prior to the appointment, when practicable. 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 in which the beneficiary indicated interest, but did not agree to discuss in advance, the Plan/Part D Sponsor must document a second scope of appointment (SOA) for the additional product type to continue the marketing appointment.

SOA documentation is subject to the following requirements:

- The documentation may be in writing, in the form of a signed agreement by the beneficiary, or a recorded oral agreement. Any technology (e.g., conference calls, fax machines, designated recording line, pre-paid envelopes, and email) can be used to document the scope of appointment.
- Date of appointment
- Beneficiary contact information (e.g., name, address, telephone number)

- Documentation of beneficiary or appointed/authorized representative agreement
- The product type(s) (e.g., MA, PDP, MMP) the beneficiary has agreed to discuss during the scheduled appointment
- Agent information (e.g., name and contact information)
- An explanation why the SOA was not documented 48 hours prior to the appointment, if applicable
- A statement clarifying that:
    - beneficiaries are not obligated to enroll in a plan
    - current or future Medicare enrollment status will not be impacted
    - that the beneficiary is not automatically enrolled in the plan(s) discussed

A beneficiary may sign an SOA at a marketing/sales event for a future appointment. Marketing/sales events, as defined in section 70.9, do not require documentation of beneficiary agreement.

> Note: All business reply cards (BRC) used for documenting a beneficiary's SOA, agreement to be contacted, confirmation of attendance to a sales event, or request for additional information must be submitted in HPMS. 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.

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 SOA 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

PFFS plans must provide CMS with their plan terms and conditions of payment contact and website information via HPMS. 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(e), (j), and (k), 423.2268(e), (j), and (k)

Plans/Part D Sponsors that have agreements with providers in connection with plan activities should ensure that those agreements address marketing activity in a manner consistent with Medicare regulations. Plans/Part D Sponsors should ensure that if a provider advertises non-health related items or services, such advertisement does not suggest or imply a relationship with or coverage by the Medicare plan.

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, recreational, or conference rooms. If a pharmacy counter area is located within a retail store, common areas would include the space outside of where individuals 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 beneficiaries in areas where individuals 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 individuals 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 and/or facilities to distribute and/or make available, Plan/Part D Sponsor marketing materials as long as the provider and/or the facility 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/facility agrees to make available and/or distribute plan marketing materials and accept future requests from other Plans/Part D Sponsors with which the provider/facility participates. Plans/Part D Sponsors may also provide materials for a provider's/facility's common area, such as the waiting room. Additionally, Plans/Part D Sponsors may provide long-term care facilities with materials for admission packets announcing all plan contractual relationships.

SNPs may provide long term care facility staff, an explanatory brochure for each I-SNP with which the facility contracts. This material may only be distributed to residents who meet the I-SNP criteria for enrollment. The brochure may explain 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)

Although providers may not be fully aware of all plan benefits and costs and may face conflicting incentives when acting as a Plan/Part D Sponsor representative, Plans/Part D Sponsors may not prohibit contracted providers

from engaging in discussions with beneficiaries should a beneficiary seek advice. To ensure that providers do not appear to be a Plan/Part D Sponsor agent, 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. Plans/Part D Sponsors should ensure that a provider assists a beneficiary in an objective assessment of his/her needs and potential options to meet those needs. Plans/Part D Sponsors should ensure that any assistance provided to a beneficiary by a contractual, co-branded, or otherwise affiliated provider, results in a plan selection that is always in the best interest of the beneficiary.

Plans/Part D Sponsors may not allow providers to:

- 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 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 enrollment activities
- Distribute materials/applications within an exam room setting

Plans/Part D Sponsors may 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 in common areas

- 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 – Provider Affiliation Announcements

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

Plans/Part D Sponsors may allow contracted providers to announce new or continuing affiliations with specific Plans/Part D Sponsors.

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

New provider affiliation announcements may be made once within the first 30 days of a new contract agreement. In the announcement, Plans/Part D Sponsors may allow contracted providers to name only one (1) Plan/Part D Sponsor. This may be done through direct mail, email, or by telephone. Neither the Plan/Part D Sponsor nor the contracted provider is required to notify beneficiaries that the provider may contract with other Plans/Part D Sponsors in new affiliation announcements.

Any provider affiliation announcement materials that describe plan benefits, premiums, or cost sharing, must be submitted through HPMS. Materials that only announce the affiliation do not need to be submitted through HPMS.

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 served, or specific benefits. 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 plans with which the provider contracts. 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. 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 during usual business hours for both current and prospective enrollees, seven (7) days a week, from at least 8:00 a.m. to 8:00 p.m. (according to the time zones for the regions in which they operate). 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 mailbox. A customer service representative must then return the call in a timely manner, no more than one (1) business day later.

> Note: From February 15 to September 30, Plans/Part D Sponsors may use alternative technologies on Saturdays, Sundays, and Federal holidays.

The use of a call center and the provision of information through a call center is a mandatory requirement for all Plans/Part D Sponsors; CMS will consider call centers compliant if they meet the following operating standards:

- Provide information in response to inquiries outlined in sections 80.2-80.4.

  Note: If callers are transferred to a third party for provision of the information listed in sections 80.2 and 80.4, all other requirements in section 80.1 apply to the services as performed by 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." Interpreters should be available within seven (7) minutes of reaching the CSR.
- Provide TTY service to all hearing impaired beneficiaries. CSRs available through the TTY service should be available within seven (7) minutes of the time of answer.
- 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 80 percent of incoming calls within 30 seconds.
- Limit the disconnect rate of all incoming calls to five (5) percent. A disconnected call is defined as a call that is unexpectedly dropped by the Plan/Part D Sponsor while the caller was navigating the IVR or connected with a CSR.

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. Plans/Part D Sponsors are prohibited from using hold time messages to sell other products.

For Pharmacy Technical Help or Coverage Determinations and Appeals Call Center requirements, refer to Appendix 3.

80.2 – 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. In some instances, a beneficiary may initiate a request for information and subsequently request enrollment into a plan. Informational calls may lead to sales/enrollment calls (or transfer to the appropriate sales/enrollment department). However, such enrollment transfers may only come 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 (if state law allows CSRs to process enrollments) 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 do not mislead or confuse Medicare beneficiaries or misrepresent the Plan/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-PDs)
- Information on how to obtain needed forms
- Information on replacing a 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, HICN) except as required to verify membership, determine enrollment eligibility or process an enrollment request
- Use language in scripts that imply they are recommended or endorsed by, calling on behalf of or asked to call the enrollee by CMS, Medicare or DHHS.
- 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 via an outbound call, 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 – Enrollment Scripts/Calls

42 CFR 422.60(c), 423.32(b)

Plans/Part D Sponsors must submit enrollment scripts into HPMS. Plans/Part D Sponsors should incorporate all relevant requirements outlined in these Guidelines (e.g., hours of operation) into their scripts.

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 Chapter 2 and Chapter 17, Subchapter D, of the Medicare Managed Care Manual, as well as Chapter 3 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); and
- Provide contact information for questions including toll-free telephone and TTY numbers.

  Note: Plans may accept enrollment requests via an incoming (in-bound) telephone call only. Outbound calls are permitted for enrollment verification purposes (see section 70.7).

80.4 – 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 not acceptable). Plans/Part D Sponsors must follow all guidance in sections 70.4 and 70.5. This guidance also extends to telephone sales services provided on behalf of the Plan/Part D Sponsor by all downstream contractors.

In addition, when a beneficiary makes an inbound call directly to a sales department or agent, the sales department or 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 beneficiary, ideally with a yes/no question.

Outbound sales calls must include a privacy statement clarifying that the beneficiary is not required to provide any health related information to the sales agent 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 marketing 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 materials inaccurate or misleading.

90.2 – Material Submission Process

42 CFR 422.2262, 423.2262

Plans/Part D Sponsors must submit marketing materials for review through the Marketing Module of HPMS, which is an automated tool used to enter, track, and maintain materials submitted to CMS for review and approval. The HPMS Marketing Module User Guide provides extensive information on how to use HPMS. Plans/Part D Sponsors should refer to the User Guide for any questions regarding the Marketing Module or how to submit 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.

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

90.2.1 – Submission of Non-English and Alternate Format Materials
42 CFR 422.2262, 422.2264(e), 423.2262, 423.2264(e)

Non-English and alternate format material must either be based on previously approved or accepted English/standard print versions of the same material, or include a back translation with the non-English/Alternate Format material submission. Both non-English and alternate format materials should be submitted as Alternate Format materials in HPMS. If the alternate format cannot be submitted to HPMS (e.g., braille), the Plan/Part D Sponsor should contact their Account Manager about other methods of submission.

> Note: Plans/Part D Sponsors do not need to resubmit large print materials as an Alternate Format material in HPMS, as long as the only change to the material is an increased font size and layout changes due to the increased font size.

Plans/Part D Sponsors may also submit multi-lingual material that contains English and another language (or languages). A material will only qualify as multi-lingual if it always incorporates English and the other language(s). Plans/Part D Sponsors should include a note in the comments field specifying that the material is multi-lingual. Multi-lingual material should not be submitted as an Alternate Format material in HPMS.

Any changes or revisions that are made to the original English version should be accurately reflected in non-English and alternate format material 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 in HPMS all required website content listed in section 100 for review. Plans/Part D Sponsors should submit their websites via links on a document. CMS reviewers should be able 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 on a document is not acceptable. If the option to view online is not feasible, the Plan/Part D Sponsor should contact their Account Manager prior to submission to request and receive permission to submit information in a manner other than a live link.

Once a Plan's/Part D Sponsor's website is reviewed and approved in its entirety, the Plan/Part D Sponsor may update specific pages of the same

website by submitting only the pages to be changed via links on a document. Any updates to pages should be submitted with their own unique material ID and date stamped accordingly. Plans/Part D Sponsors must resubmit webpages for review when changes are made to plan benefits, premiums, or cost-sharing.

Plans/Part D Sponsors may make the website available for public use during the CMS review period; however, Plans/Part D Sponsors must indicate that the website is pending CMS review until CMS has either approved or disapproved the website. If the website or portions of the website are disapproved, Plans/Part D Sponsors must submit the revision to CMS within 20 days.

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 by CMS.

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 materials that are created by a third-party on behalf of several Plans/Part D Sponsors. Plans/Part D Sponsors are accountable for the marketing practices of their third-party organizations and must ensure that all materials developed on their behalf are compliant with CMS requirements.

Relevant terms for the multi-plan submission 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**) – A contracted Plan/Part D Sponsor that produces and submits the Auxiliary Material to CMS, based on the approved Primary Material.

When submitting multi-plan marketing material, the CE that develops the material must coordinate with the LP to obtain CMS' approval. 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 marketing code, so the NLPs may submit their auxiliary materials in HPMS. Communications pertaining to this process should be documented for tracking purposes.

The LP must insert the following in the applicable comment fields in HPMS:

- "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 submit the "Auxiliary" material in HPMS using the same category that was selected for the "Primary" material.

To be eligible for the multi-plan submission process, the "Auxiliary" material must be submitted within 60 days of the approval/acceptance of the "Primary" material. Materials that do not meet this criterion will undergo the standard material review process.

Additionally, 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. Materials that have additional modifications are not eligible for the multi-plan submission process.

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 approved by the Plan's/Part D Sponsor's CMS Account Manager or designated CMS reviewer. 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 Plan/Part D Sponsor should also include the name, phone, and email contact of the CE.

90.2.4 – Submission of Mobile Applications

42 CFR 422.2262, 423.2262

If a Plan/Part D Sponsor would like to use a mobile application (app) for marketing to prospective enrollees, the mobile app must be submitted for approval (see section 100.7). A Plan/Part D Sponsor should submit a document in HPMS with either:

- A link to access the mobile app online; or

- A statement that the app will be submitted to the Account Manager outside of HPMS. Include the name(s) of the person(s) at CMS who will receive the app for review.

It is not acceptable to submit screen shots or text on a separate document. If the option to view the mobile app online is not feasible, the Plan/Part D Sponsor should contact their Account Manager to discuss how they will provide access to the app.

90.3 – HPMS Material Statuses

42 CFR 422.2262, 423.2262

All marketing materials in HPMS will have an indication of their disposition, such as a final status of accepted, approved, disapproved, deemed, withdrawn, alternate format, SA/LIS, or populated template.

> Note: If a Plan/Part D Sponsor does not have an executed contract with CMS, all submitted marketing material will be considered and marked as conditional.

90.3.1 - Approved

42 CFR 422.2262, 423.2262

Material marked as "approved" 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 previously approved marketing materials, if they are found to be inaccurate, altered, or otherwise non-compliant.

90.3.2 - Disapproved

42 CFR 422.2262, 423.2262

Material marked as "disapproved" indicates that the material does not comply with applicable standards, such as regulations, laws, and standards discussed in the MMG 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 can be used by the Plan/Part D Sponsor. The following conditions will apply:

- Materials subject to a 45 day review period will be given the status of "deemed" on the 46th day.

- Materials subject to a 10 day review period will be given a status of "deemed" on the 11th day.

- Marketing materials from a Plan/Part D Sponsor without an executed contract with CMS will receive a conditional deemed approval. After the contract is awarded, the material disposition will be changed to "deemed" and can be used by the Plan/Part D Sponsor.

90.3.4 – Withdrawn
42 CFR 422.2262, 423.2262

Plans/Part D Sponsors may request to withdraw a marketing submission prior to CMS reviewing the material. Plans/Part D Sponsors should submit a written request to their Account Manager or Marketing Reviewer stating the reason(s) for the withdrawal.

90.3.5 – Accepted
42 CFR 422.2262, 423.2262

A material status of "accepted" indicates that the material, submitted as File & Use, is accepted for use in the format in which it was submitted. The material 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 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

When submitted in HPMS, non-English and alternate format materials will receive a status of "Alternate Format".

Populated standard templates should be submitted in HPMS under "Final Expedited Review" codes. These documents will receive a status of "Populated Template (see section 90.8.2).

The SA/LIS material status applies to special categories of materials. Please see the HPMS User Guide for an explanation of when this status is applicable.

90.4 - Resubmitting Previously Disapproved Pieces
42 CFR 422.2262, 423.2262

Plans/Part D Sponsors should clearly indicate all changes/updates made to a material, which has been previously disapproved, when it is resubmitted. This will expedite the review process. Plans/Part D Sponsors should highlight

any text changes and/or insert 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 in HPMS for prospective review will have a review timeframe of 10 or 45 days. The marketing review time period begins on the date a material is submitted in HPMS.

90.6 - File & Use Process

42 CFR 422.2262(b), 423.2262(b)

Under the File & Use process, Plans/Part D Sponsors must submit eligible marketing materials in HPMS at least five (5) calendar days prior to their distribution and certify that the materials comply with this guidance.

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

Plans/Part D Sponsors without an executed contract with CMS may submit File & Use materials. Once the contract is executed, the appropriate officer of the Plan/Part D Sponsor is essentially attesting to the Plan's/Part D Sponsor's compliance with the File & Use 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 their 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)

Plans/Part D Sponsors may lose File & Use Certification status or face compliance action if they:

- Submit or use materials that do not meet the requirements of this guidance; or

- Fail to file material(s) at least five (5) calendar days prior to their distribution.

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), 423.2264

CMS will periodically conduct retrospective reviews of materials that were submitted under File & Use to ensure compliance by those Plans/Part D Sponsors that utilize this process.

90.7 – Model Marketing Materials and Language
42 CFR 422.2262(c), 423.2262(c)

CMS defines two different types of model marketing materials – standardized and non-standardized. These material types affect the Plan's/Part D Sponsor's timing of use and ability to make changes to the documents. Regardless as to the type of model marketing material, in general, when a Plan/Part D Sponsor uses a CMS provided model without modification, it results in a 10 day marketing review period or it may be submitted via File & Use. 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.

"Without modification" means the Plan/Part D Sponsor used CMS model language verbatim.

90.7.1 – Standardized Model Materials
42 CFR 422.2262(c), 423.2262(c)

Standardized model materials are marketing materials created and provided by CMS that, other than the limited exceptions provided below, 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 the standardized materials:

- Populating variable fields;
- Correcting grammatical errors;

- Adding customer service phone numbers;
- Adding plan name/logo; and
- Adding the CMS marketing material identification number.

90.7.2 – Non-Standardized Model Materials
42 CFR 422.2262(c), 423.2262(c)

Unlike standardized model materials, the use of non-standardized model materials is at the discretion of the Plan/Part D Sponsor. 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. In addition, any change made to a non-standardized model material, except as noted below, will result in that material being subject to a 45 day review period.

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

- Populating variable fields;
- Adding fields for 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;
- 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 modification made to the document will make the material subject to the standard 45 day review process and/or ineligible for File & Use submission.

> Note: D-SNPs may remove references to LIS from model materials.

90.7.3 – 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.

90.8 - Template Materials

42 CFR 422.2262, 423.2262

"Template materials" are materials that include 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 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 non-variable text in a template must be submitted in HPMS. 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 make corrections for prospective enrollees and send errata sheets/addenda/reprints to current enrollees within a reasonable timeframe.

> Note: Identical materials submitted separately and not noted as template materials are subject to separate review.

90.8.1 - Static Templates

42 CFR 422.2262, 423.2262

Template material is considered "static" 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 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 populated static templates are not resubmitted, Plans/Part D Sponsors are not required to indicate that the unpopulated submission is a template when submitting the material in HPMS.

90.8.2 - Standard Templates

42 CFR 422.2262, 423.2262

Marketing materials that include placeholders for variable data not listed in section 90.8.1, such as plan specific benefits, premiums, and cost sharing, are considered "standard" templates. Plans/Part D Sponsors must submit final, populated versions of standard templates in the HPMS Marketing Module using the associated "Final Expedited Review" code within 30 days of use. If the template does not have a "Final Expedited Review" code, Plans/Part D Sponsors may not submit the document as a standard template. The document must instead be submitted with all fields populated, other than those listed in section 90.8.1. 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, Plans/Part D Sponsors may be required to remedy the error by providing enrollees with updated information via errata sheets or addenda.

Similarly, 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 enrollees 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 may 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; and
- 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

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 should not provide links to foreign drug sales. This includes links from advertisements that appear on the Plan's/Part D Sponsor's website.

Plans/Part D Sponsors should note that there may be additional non-marketing website requirements found in the Medicare Managed Care Manual, the Prescription Drug Benefit Manual, and HPMS memorandums or

emails. Updates to marketing website requirements may also be released through HPMS memoranda or emails.

100.1 – General Website Requirements

Plans/Part D Sponsors must:

- Maintain their current contract year website for current beneficiaries through December 31 of each year.
- Post the following information on the website on September 30 for the upcoming contract year:
    - Annual Notice of Change/Evidence of Coverage
    - Provider and/or Pharmacy Directory
    - Formulary and Utilization Management Documents
    - Multi-Language Insert
- Notify individuals that s/he will leave the Plan's/Part D Sponsor's Medicare information website, if there is a link that will take an individual to non-Medicare information or to a different website.
- Ensure all websites that market the Plan's/Part D Sponsor's products are in compliance with the applicable requirements.

Plan/Part D Sponsor websites must not:

- Include content that discusses plan-specific benefits, premiums, cost-sharing, or Star Ratings for products offered in the next contract year prior to October 1.
- Require any information be entered by an individual, other than a zip code, county, and/or state for access to non-beneficiary specific website content.
- Include notification that Plan/Part D Sponsor is not responsible for the content of their social media pages or the websites of any downstream entity that provides information on the Plan/Part D Sponsor's behalf.

All Plans/Part D Sponsors are expected to:

- Maintain a separate and distinct section on their website for their Medicare information, if the Plan/Part D Sponsor markets other lines of business.
- Review and update website content at least monthly. See section 90.2.2 for instructions about when these updates require resubmission of webpages for approval.
- Note that the status of the website is "pending" until CMS has granted an approval/disapproval (see section 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 each webpage with the date the page was last updated.
- Clearly label any links.

100.2 – Required Content

42 CFR 422.111(b) and (h)(2), 42 CFR 423.128(b) and (d)(2)

All Plans/Part D Sponsors must include the following information on their website:

- The toll-free customer service number and hours of operation, TTY number, and either a physical or Post Office Box address;
- Information on beneficiaries' and Plans'/Part D Sponsors' rights and responsibilities upon disenrollment;
- The Plan/Part D Sponsor service area;
- A list of premiums and cost-sharing (e.g., co-payments, co-insurance and deductibles), including any conditions and limitations;
- All out-of-network coverage rules;
- Instructions on how to appoint a representative and a link to the downloadable version of the CMS Appointment of Representative Form (CMS Form-1696); and
- A description of and information on how to file a grievance, an organizational/coverage determination, and an appeal. This must include:

- Procedures for filing an organizational/coverage determination, a grievance, and an appeal;

- A direct link to the Medicare.gov complaint website at: https://www.medicare.gov/MedicareComplaintForm/home.aspx, where a enrollee can enter a complaint in lieu of calling 1-800-Medicare;

- 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; and

- Contact numbers for enrollees and/or physicians to use for process or status questions.

PFFS Plan websites must also include a link to Plan's/Part D Sponsor's Terms and Conditions of Payment.

MSA Plan websites must also 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 – Part D Sponsor Required Content

42 CFR 423.128(b) and (d)

In addition to the requirements in section 100.2, Part D Sponsor's websites must include:

- Immediate access to the coverage determination and redetermination processes through a secure location prominently displayed on the website; and
- Quality assurance policies and procedures, including Medication Therapy Management (MTM) information, and drug and/or utilization management information.

Part D Sponsors are also expected to include a separate section or page about MTM programs, written in plain language appropriate for enrollees, including:

- Part D Sponsors' specific eligibility requirements;
- A statement informing enrollees about who to contact at the Part D Sponsor for more information, with customer service personnel prepared to answer questions about the MTM program;
- A 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 enrollees;
- A description of how the enrollee 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; and
- A statement on how the enrollee may obtain MTM service documents, including a blank copy of the Personal Medication List posted on the website. A statement clarifying that these programs are not considered a benefit.

100.2.2 – Required Documents for All Plans/Part D Sponsors
42 CFR 422.111(b) and (h), 423.128(b) and (d), 164.520(c)

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 directory and/or pharmacy directory, as applicable (see section 100.4 for Online Provider/Pharmacy Directory requirements);
- 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; and
- All required translated materials identified in sections 30.6, 30.7, and 30.9, 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 five (5) percent language threshold.

CMS expects Plans/Part D Sponsors to post the following on the Plan/Part D Sponsor website:

- Enrollment instructions and forms;
- Any form to be used by physicians when providing a supporting statement for an exceptions request; and
- Any form to be used by a physician or enrollee to satisfy a prior authorization or other utilization management requirement.

Additionally, Part D Sponsors must post the following documents:

- Current Comprehensive Formulary (see section 100.5 for detailed requirements);
- Utilization Management Documents;
- Prescription Drug Transition Policy;
- LIS Premium Summary Chart; and
- CMS Part D Model Coverage Determination and Redetermination Request Forms.

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; and

- SNPs, section 1876 cost plans, and Religious Fraternal Benefit plans may, but are not required to, accept enrollment requests through the OEC.

Plans/Part D Sponsors may also 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. Plans/Part D Sponsors may obtain technical and related services from outside entities in support of its online enrollment mechanism, such as licensed software.

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 section 90.2.2).

Plans/Part D Sponsors may use downstream entities, such as an agent/broker or third party website, as a means of facilitating enrollment requests and capturing the enrollment request. However, Plans/Part D Sponsors retain complete responsibility for the appropriate handling of any sensitive beneficiary information provided as part of electronic enrollment, including those portions of the process that are facilitated or managed by downstream entities.

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 requirements.

100.4 – Online Provider/Pharmacy Directory Requirements

42 CFR 422.111(b)(3) and (h)(2)(ii), 422.112, 423.128(d)(2)

Plans/Part D Sponsors must post a provider and/or pharmacy directory for all products offered by service areas or by general geographic area. The provision of accurate provider/pharmacy information and ensuring adequate access to covered services are essential protections for enrollees. Accurate provider/pharmacy directories are critical to helping enrollees make educated decisions about their MA/Part D plan choices. These directories must contain all the information required in the provider/pharmacy (as applicable) directory models located at: (http://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/MarketngModelsStandardDocumentsandEducationalMaterial.html). In addition, the online provider directory must contain a special notation to highlight providers that are not accepting new patients.

The following formats for the online provider/pharmacy directory are acceptable:

- A searchable "master" provider directory that represents the complete network for the Plan/Part D Sponsor.
- Individual provider directories by plan product and/or service area (e.g., mirroring those that will be printed for the Plan/Part D Sponsor membership).
- A search engine. If a Plan/Part D Sponsor uses only a search engine on its website, it must meet all the requirements for the model Directory.

Plans should contact their network/contracted providers on a monthly basis to update the following information in the online provider directory:

- Ability to accept new patients;
- Street address;
- Phone number;
- Office hours; and
- Any other changes that affect availability to patients.

Plans/Part D Sponsors are also expected to update directory information any time they become aware of changes. All updates to the online provider/pharmacy directory are expected to be done in real-time.

See section 60.4 for additional information about Provider/Pharmacy Directory requirements.

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

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

The online formulary must be the Part D Sponsor's comprehensive formulary and the Part D Sponsors must provide a definition of a comprehensive formulary. It must display all information contained within the HPMS approved formulary files and meet all the requirements of the model comprehensive formulary. Part D Sponsors may make minor modifications to address issues such as abbreviations and/or grammatical truncation.

The online formulary should be downloadable. Part D Sponsors may also provide an online formulary search tool, but the search tool should not substitute for the downloadable formulary.

The downloadable formulary, any search tools, and utilization management documents are expected to:

- Be updated at least once per month; and
- 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".

If a search tool is provided, it should be searchable by drug name. When search results indicate a drug is not covered, it should provide an explanation or a 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.

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. Each search result that appears in the search tool is expected to:

- 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 are also expected to be included.

- Include the following statement: "This drug may be covered under Medicare Part B or Part D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination," for drugs with a Part B versus Part D administrative prior authorization requirement.

- 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).

Part D Sponsors may post online the notice of formulary changes, provided that it:

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

100.6 – Social Media

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

Plans/Part D Sponsors must submit to HPMS social media (e.g., Facebook, Twitter, YouTube, LinkedIn, Scan Code, or QR Code) posts that meet the definition of marketing materials, specifically those that contain plan-specific benefits, premiums, cost-sharing, or Star Ratings.

Plans/Part D Sponsors must not include content on social/electronic media that discusses plan-specific benefits, premiums, cost-sharing, or Star Ratings for products offered in the next contract year prior to October 1.

If a Plan/Part D Sponsor posts required information (see sections 100.2 and 100.3) 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. Both plan enrollees and members of the public should be able to view the required information without having to join a third-party social media website.

Additional guidance on social media has been incorporated into relevant sections of the MMG. For example, see section 40.1 for information on social media and material IDs, section 50 for information on social media and disclaimers, and section 70.9 or information on virtual events held through social media.

100.7 – Mobile Applications

42 CFR 422.2260, 422.2262, 422.2268, 423.2260, 423.2262, 423.2268

Mobile applications (apps) that provide information to current enrollees about their current Plan or provide non-Plan-specific health information do not require submission to HPMS for marketing review. If the app is targeted to potential enrollees, it must be submitted in HPMS. Plans/Part D Sponsors must also provide CMS access to their mobile apps upon request.

If Plans/Part D Sponsors do not provide complete plan benefit, premium, and co-payment information in the app, the selection of information must not be misleading. The app must also instruct beneficiaries where to find complete information.

If the mobile app contains provider and/or pharmacy directory information, it must include and give equal prominence to all in-network providers/pharmacies, although it may limit the information by geographic area and/or by the search criteria. The app must clearly indicate if it limits the information to a geographic area.

110 - Reserved

120 – Marketing and Sales Oversight and Responsibilities

120.1 – Compliance with State Licensure and Appointment Laws

42 CFR 422.2272(c), 423.2272(c)

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

120.2 – Plan Reporting of Terminated Agents

42 CFR 422.2272(c)-(e), 422.2274(f), 423.2272(c)-(e), 423.2274(f)

Plans/Part D Sponsors must report the termination of any agents/brokers to the State (adhering to state requirements for reporting terminations to the state) and the reasons for the termination, if State law requires the reasons to be reported. Plans/Part D Sponsors must report for-cause terminations to CMS Account Managers, via email or letter. Plans/Part D Sponsors must also report to CMS Account Managers any sales of Medicare products which were made by agents without a valid license.

If a Plan/Part D Sponsor discovers an enrollment application was submitted by an unlicensed agent or broker, the Plan/Part D Sponsor must immediately terminate the agent or broker and report this action to 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)(i) or 423.38(c)(8)(i).

120.3 – Agent/Broker Training and Testing

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

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 provides updated guidance 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, 423.2274

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; or
- Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials.

Initial Compensation:

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

Renewal Compensation:

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

Referral/Finder's Fees:
Referral/Finder's fees paid to agents and brokers, including independent, employed, and captive agents and brokers, may not exceed $100 ($25 for PDPs). This amount is not reasonably expected to provide enough financial incentive for an agent or broker to recommend or enroll a beneficiary into a plan that is not the most appropriate for the beneficiary's needs.

Additionally, referral/finder's fees paid to all agents and brokers must be part of total compensation and must not exceed FMV for that contract year.

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

42 CFR 422.2272(c)-(e), 422.2274(c) and (d), 423.2272(c)-(e), 423.2274(c) and (d)

Plans/Part D Sponsors may not pay compensation to agents/brokers that do not meet state 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 an agent/broker contract, any future payment of existing business will be governed by the terms of the contract, subject to the limits in the regulation.

Note: Non-agents/brokers receiving referral fees are not subject to the general compensation rules (e.g., training/testing/licensure).

120.4.2 – Compensation Payment Requirements

42 CFR 422.2274(a), (b)(4), and (g), 423.2274(a), (b)(4), and (g), 422.516 (a)(6), 423.514 (a)(5)

Each year, Plans/Part D Sponsors may decide whether they are using employed, captive, and/or independent agents, as well as the amount within CMS' FMV limits they will compensate independent agents/brokers. Each year, CMS issues an HPMS memo that notifies Plans/Part D Sponsors of the FMV, and requires them to inform CMS yearly by the end of July whether they will use agents/brokers, including the types of agents/brokers, as well as the compensation payment ranges.

In addition, Plans/Part D Sponsors must have in place their full agent/broker compensation structure for new and renewal enrollments by October 1 each year. This structure supports the compensation payment ranges submitted earlier in the year and must be made available to CMS upon request. The compensation structure includes how the Plan/Part D Sponsor plans to disseminate compensation to the agent/broker.

The agent/broker compensation year is January 1 to December 31. Compensation payments must be calculated on a January to December enrollment year. They may not be made on a rolling basis or on an enrollment year basis. For example, if a beneficiary's enrollment is effective September 1, then the initial enrollment year for that beneficiary ends on December 31 and the beneficiary's "renewal" year would begin in January of the following year. Plans/Part D Sponsors should consult the MARx agent/broker compensation report to determine whether an initial or renewal payment is appropriate. This report is automatically released and disseminated monthly by the MARx system.

Plans/Part D Sponsors have the flexibility to make compensation payments annually, quarterly, monthly, or by a different schedule. However, compensation payments must be paid during the year of enrollment. In other words, enrollments during the preceding year for effective dates January 1 (or later) of the following year, should not be compensated until January 1 or after. Payments for enrollments effective at any point during a calendar year must be paid in full by December 31 of the calendar year of enrollment. In addition, compensation payments should be based on the number of months a beneficiary is enrolled during a calendar year.

Referral/finder's fees may not exceed the amounts stated in section 120.4. In addition, referral fees paid to agents must be part of total compensation, not to exceed the FMV for initials and 50% of FMV for referrals.

Plans/Part D Sponsors that contract with third-parties to sell MA/Part D products must ensure that compensation payments to these third-parties are no greater than the Plans'/Part D sponsors' initial and renewal compensation amounts.

Full or pro-rated initial compensation may be paid to agent/brokers under the following three scenarios:

(1) The beneficiary's first year of enrollment in an MA plan or MA-PD plan;

(2) When a beneficiary enrolls in an "unlike plan type," during their renewal year; or

(3) When a beneficiary moves from an employer group plan to a non-employer group plan (either within the same Parent Organization or between Parent Organizations) counts as an initial enrollment.

Renewal compensation may be paid to agents/brokers under the following three scenarios:

(1) Following the initial year compensation;

(2) When a beneficiary enrolls in a new "like plan" within the same Parent Organization or between two different Parent Organizations; or

(3) When a beneficiary enrolled in an MMP switches to an MA plan or an MA-PD plan (and vice versa), if applicable per state MMP policy.

Initial compensation must be pro-rated to agents/brokers under the following scenario:

(1) When a beneficiary changes plans during their initial enrollment. The compensation payment is based on the number of months the beneficiary was enrolled in the plan. For example, if an initial enrollment changes from one Parent Organization to another Parent Organization for a May 1 effective date, the new Parent

Organization must pay 8/12ths of the initial compensation to the agent/broker.

Other compensation scenarios are highlighted below:

(1) Either an initial compensation or a pro-rated compensation should be paid when a beneficiary enrolls in a plan and has no prior plan history. If the pro-rated compensation is used, it should be based on the number of months the beneficiary is enrolled.

(2) *Only* the MA compensation amount should be paid when a beneficiary enrolls in an MA-PD plan, not the MA compensation amount *and* the PDP compensation amount.

(3) When a beneficiary enrolls in both a section 1876 cost plan and a stand-alone PDP, compensation should be paid for both enrollments).

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 FMV and 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, 423.2274

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 State-licensed marketing representatives, unless otherwise stated by state law. 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; and
- "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

Plans offering employer group health plans are not required to submit informational copies of their dissemination materials to CMS at the time of use. However, as a condition of CMS providing particular waivers or modifications to employer group plans, 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.

CMS waivers to employer group plans are limited in scope to their stated parameters, and employer group waiver plans 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.

Table 130.1 - Marketing Provisions – Employer/Union Group Plans

Marketing Provisions that apply to Employer/Union Group Plans These requirements are applicable for the transaction between the agent/broker selling the plan to the employer/union. All activities conducted by the employer/union or its designees to sign up individual employees to the plan(s) selected by the employer/union are excluded from these provisions. Note: This table contains a partial list of exclusions.	
Applicable Provisions (Not Waived)	**Not Applicable Provisions (Waived)**
Nominal Gifts	Unsolicited Contacts
Sales/Marketing in Health Care Settings	Cross-selling
Sales/Marketing at Educational Events	Scope of Appointments
Co-branding	Provision of Meals
Appointment of Agents/Brokers	Agent/Broker Compensation
State Licensed	Agent/Broker Testing
Reporting of Terminated Agents/Brokers	
Agent/Broker Training 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.	

140 – Reserved

150 – Use of Medicare Mark for Part D Sponsors

Section 1140 of the Social Security Act

All Part D Sponsors must 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.

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.

Unless otherwise approved, no individuals, organizations, and/or commercial firms may distribute materials bearing the Medicare Prescription Drug Benefit Program Mark.

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; and

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:

Office of the Administrator/Office of Communications Visual & Multimedia
Communications Group
7500 Security Blvd.
Baltimore, MD 21244-1850

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 – 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.

150.5 – 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.

150.5.1 – 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.

150.5.2 – 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.

150.5.3 – 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.

150.5.4 – 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.

150.5.5 – 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.

150.5.6 – 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.

150.5.7 – 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-eight (1/8) inch safety from any edge;

- Do not use any of the mark elements to create a new mark or graphic; and
- Do not use the mark on background colors, images or other artwork that interfere with the legibility of the mark.

150.6 – 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

In addition to limits CMS places on the data it provides to Plans/Part D Sponsors, compliance with the HIPAA privacy and security rules (45 CFR Parts 160, 164) may require greater protection of information from and/or about enrollees. Plans/Part D Sponsors should also consult with their counsel and the many resources offered by the HHS' Office for Civil Rights (OCR) to ensure their compliance with the HIPAA requirements. CMS does NOT provide guidance on HIPAA privacy and security compliance; the OCR provides such guidance. These Marketing Guidelines are about compliance with CMS and Medicare requirements only. For information on HIPAA privacy and security requirements, please visit:

http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/privacyguidance.html

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 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; or
- Medigap policies.

While it is important to protect Medicare beneficiaries from potentially unwelcome marketing and other communications, we also recognize Plans'/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 section 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;
- 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; and
- Information on Medicaid and other community or social services program.

160.2 – When Prior Authorization from the Beneficiary Is Required

To comply with CMS and Medicare policies and rules, Plans/Part D Sponsors must obtain authorization from an enrollee prior to using or disclosing the enrollee's protected health information for marketing purposes. 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; and
- Joining grassroots advocacy organizations and information about such advocacy.

160.3 – Obtaining Prior Authorization

To comply with CMS and Medicare policies and rules, Plans/Part D Sponsors must receive the enrollee's "opt-in" authorization prior to sending any non-plan or non-health related information. Plans/Part D Sponsors should keep evidence of authorization for audit purposes. Following are examples of how the authorization required under section 160.2 may be obtained.

- Plans/Part D Sponsors may send, at their own expense, written authorization "opt-in" forms to enrollees.

- Plans/Part D Sponsors may direct an enrollee to a website to provide consent. If the Plan/Part D Sponsor uses a website for the "opt-in" process, the link from the plan's Medicare product website must inform the enrollee 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 enrollee will receive additional information that may be non-plan or non-health related.

- Enrollees can complete a written authorization in person at marketing events, health fairs, or other public venues.

- Enrollees can complete the authorization over the telephone, provided the authorization is recorded. The call must be a enrollee-initiated inbound telephone call and scripts for such calls must comply with all guidance in section 80.

- Enrollees can complete the authorization via an email to the plan, provided that the authorization includes an electronic signature.

Regardless of the method by which the 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 submitted in 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.

Compliance with the HIPAA privacy and security rules (45 CFR Parts 160, 164) may require greater protection of information from and/or about enrollees. Plans/Part D Sponsors should also consult with their counsel and the many resources offered by the HHS' Office for Civil Rights (OCR) to ensure their compliance with the HIPAA requirements. CMS does NOT provide guidance on HIPAA privacy and security compliance; the OCR provides such guidance. 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.

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 do not include information about the plan's benefit structure. In addition, these communication materials are not tied to regularly occurring events such as aging into Medicare, the Annual Enrollment Period, or a new contract year. These materials are not considered marketing materials. Examples 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 an enrollee is receiving a refund or is being billed for underpayments;
- Letters describing enrollee-specific claims processing issues; or
- Correspondence pertaining to unique questions or issues that affect an individual or small subset of the plan's enrollment.

Note: 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 individuals with visual, speech, physical, hearing and intellectual disabilities (e.g., braille, large print, audio).

Banner and Banner-Like Advertisements

Banner advertisements are typically used in television ads, and flash information quickly across a screen for the sole purpose of enticing a prospective enrollee to contact the Plan/Part D Sponsor to enroll or obtain more information. A "banner-like" advertisement is usually in some media other than television, e.g., outdoor advertising and internet banner ads. Banner advertisements are intended to be 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 is when a 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 an individual to attract his/her attention or interest 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 include any informational materials targeted to Medicare beneficiaries which:

(1) Promote the Plan/Part D Sponsor, or any Plan/Part D Sponsor offered by the MA organization;
(2) Inform Medicare beneficiaries that they may enroll, or remain enrolled in, a Plan/Part D Sponsor offered by the MA organization;
(3) Explain the benefits of enrollment in a Plan/Part D Sponsor, or rules that apply to enrollees; or
(4) Explain how Medicare services are covered under a Plan/Part D Sponsor, including conditions that apply to such coverage.

Marketing materials exclude ad hoc enrollee communications materials.

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.

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

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 as a result of MTM services 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 program 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. Informational scripts are designed to respond to beneficiary questions and requests and provide objective information about a plan or the Medicare program. Sales and enrollment scripts are intended to steer a beneficiary towards a plan or limited number of plans, or 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)

Value-Added Items and Services (VAIS) are items and services that are not plan benefits, are not part of the Plans'/Part D Sponsor's benefit package and may not be marketed to prospective enrollees, or used as an inducement or incentive for enrollment. VAIS are non-Medicare covered services or items, typically discounts, offered by a VAIS provider to the enrollees of an MA plan.

> Note: VAIS information cannot be included in or bound with materials intended for prospective enrollees, or posted on parts of the website directed at prospective enrollees.

Appendix 2 – Related Laws and Regulations
(Not an exhaustive list)

Americans with Disabilities Act of 1990

Federal agencies must 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 must follow 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/.

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 must 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 794).

Section 504 of the Rehabilitation Act

All Plans/Part D Sponsors must ensure effective communication with individuals with disabilities and to provide auxiliary aids and services, such as alternate formats (e.g., braille, audio, large format), to individuals with disabilities to ensure 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 – 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; and
- 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, 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 from at least 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; and
- 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.