Chapter 3 of the Medicare Managed Care Manual
Chapter 2 of the Prescription Drug Benefit Manual

Medicare Marketing Guidelines

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

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(Rev. 97, Issued: 6-7-12)

10 – Introduction

The Medicare Marketing Guidelines (MMG) implement the Centers for Medicare & Medicaid Services' (CMS) marketing requirements and related provisions of the Medicare Advantage (MA) *(also referred to as Plan)*, Medicare Prescription Drug Plan (PDP) *(also referred to as Part D Sponsor)*, and 1876 cost contract rules *(also referred to as Plans)*, (i.e., Title 42 of the Code of Federal Regulations, Parts 422, 423, and 417). These requirements do not apply to Program of All-Inclusive Care for the Elderly (PACE) plans or section 1833 cost plans.

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

Pursuant to 42 CFR §417.428, §422.2260, and §423.2260, marketing materials include any materials developed and/or distributed by those entities covered by the MMG which are targeted to Medicare beneficiaries. While not an exhaustive list, the following materials fall under CMS' purview per the definition of marketing:

- General audience materials such as general circulation brochures, direct mail, newspapers, magazines, television, radio, billboards, yellow pages or the Internet.
- Marketing representative materials such as scripts or outlines for telemarketing or other presentations.
- Presentation materials such as slides and charts.
- Promotional materials such as brochures or leaflets, including materials circulated by physicians, other providers, or third-party entities.
- Membership communications and communication materials including membership rules, subscriber agreements, member handbooks and wallet card instructions to enrollees.
- Communications to members about contractual changes, and changes in providers, premiums, benefits, plan procedures, etc.
- Membership activities, (e.g., materials on plan policies, procedures, rules involving non-payment of premiums, confirmation of enrollment or disenrollment, or non-claim specific notification information).

- The activities of a *Plan's/Part D Sponsor's* employees, independent agents or brokers, subcontracted TMOs or other similar type organizations that are contributing to the steering of a potential enrollee toward a specific plan or limited number of plans, or may receive compensation directly or indirectly from a *Plan/Part D Sponsor* for marketing activities.

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

- *Plans/Part D Sponsors* are responsible for ensuring compliance with CMS' current marketing regulations and guidance, including monitoring and overseeing the activities of their subcontractors, downstream entities, and/or delegated entities.

- *Plans/Part D Sponsors* are responsible for full disclosure when providing information about plan benefits, policies, and procedures.

- *Plans/Part D Sponsors* are responsible for documenting compliance with all applicable MMG requirements.

It is important to note that the marketing guidance set forth in this document is subject to change as policy, communication technology, and industry marketing practices continue to evolve. Any new rulemaking or interpretative guidance, (e.g., annual Call Letter or HPMS guidance memoranda), may supersede the marketing guidance provided in this document. Specific questions regarding a marketing material or marketing practice should be directed to the *Plan/Part D Sponsor*'s Account Manager or designated Marketing Reviewer.

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

20 – Materials Not Subject To Review

42 CFR 422.2260, 422.2262, 423.2260, 423.2262

The following items are materials that are not subject to review by CMS and should not be uploaded into HPMS. However, *Plans/Part D Sponsors* are still responsible for maintaining such materials, *when applicable*, so as to make them available upon CMS request.

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

- OMB Forms

- Press releases that do not include any plan-specific information, (e.g., information about benefits, premiums, co-pays, deductible, benefits, how to enroll, networks)

- Certain member newsletters unless sections are used to enroll, disenroll, and communicate with members on product specific information, (e.g., benefits or coverage, membership operational policies, rules and/or procedures)

- Blank letterhead/fax coversheets that do not include promotional language

- General health promotion materials that do not include any specific plan related information, (e.g., health education and disease management materials). In general, health promotion materials should meet CMS' definition of "educational" (Refer to 70.9, Educational Events)

- Non-Medicare beneficiary-specific materials that do not involve an explanation or discussion of Part D, MA, or section 1876 cost plans, (e.g., notice of check return for insufficient funds, letter stating Medicare ID number provided was incorrect, billing statements/invoices, sales, and premium payment coupon book)

- Sales/marketing representative recruitment and training documents

- *The following* Medication Therapy Management (MTM) program materials:
    - *MTM program materials provided to members enrolled in their plan or materials that address issues that are unique to individual members*
    - *The Part D MTM program comprehensive medication review summary in CMS' standardized format that is provided to a beneficiary (should not include any marketing messages, marketing disclaimers, or other promotional material)*

- Ad hoc Enrollee Communications Materials (see definition in Appendix 1)

- Materials used at educational events for the education of beneficiaries and other interested parties.
- Coordination of Benefits notifications (as provided in Chapter 14 of the Medicare Prescription Drug Benefit Manual)
- Health Risk Assessments
- Mail order pharmacy election forms
- Member surveys
- VAIS materials (refer to Chapter 4 of the Medicare Managed Care Manual)
- Communicating preventive services to members
- Mid-year Change Enrollee Notifications (Refer to 60.8)
- *Materials developed by a third-party entity that is not affiliated or contracted with the Plan/Part D Sponsor (Refer to 40.11.3). An affiliation is defined as a mutual agreement of understanding (includes, but is not limited to parent organization relationships).*

30 - *Plan/Part D Sponsor* Responsibilities

30.1 - Limitations on Distribution of Marketing Materials

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

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

If there are any changes or corrections made to final materials (e.g., the benefit or cost-sharing information differs from that in the approved bid), *Plans/Part D Sponsors* must correct those materials for prospective enrollees and may be required to send errata sheets/addenda/reprints to current members. In cases where non-compliance is discovered, the *Plan/Part D*

Sponsor may be subject to compliance or enforcement actions, including intermediate sanctions and civil money penalties.

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

30.2 - Co-branding

42 CFR 422.2268*(n)*, 423.2268*(n)*

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).

30.2.1 - Co-branding with Providers or Downstream Entities

42 CFR 422.2268(n), 423.2268(n)

Plans/Part D Sponsors are prohibited from displaying the names and/or logos of co-branded providers on the *Plan/Part D Sponsor's* member identification card, unless the provider names and/or logos are related to a member's selection of a specific provider/provider organization, (e.g., physicians, hospitals, and pharmacies).

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 member ID card.

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

42 CFR 422.2268*(n),* 423.2268*(n)*

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 connection. The decision to "co-brand" with SPAPs resides with the *Plan/Part D Sponsor*.

30.*3 – Plan/Part D Sponsor* Responsibility for Subcontractor Activities and Submission of Materials for CMS Review

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

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 § 130 of this chapter, Chapter 9 of the Medicare Managed Care Manual, and Chapter 12 of the Prescription Drug Benefit Manual for more guidance.

Materials created by agents or brokers that mention plan specific benefits must be submitted by the *Plan/Part D Sponsor* to CMS. *Materials that include an agent/broker's phone number should clearly indicate that calling the agent/broker number will direct an individual to a licensed insurance agent/broker. Business cards are excluded from this requirement.*

Materials that only indicate the products, (e.g., HMO, PPO, or PDP), an agent sells are not required to be submitted to CMS. Please note that this guidance in no way precludes the application by the *Plans/Part D Sponsors* of more stringent rules or contractual obligations in order to further restrict agent or broker communication and activities.

30.*4* - Anti-Discrimination

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

Plans/Part D Sponsors may not discriminate based on race, ethnicity, national origin, religion, gender, age, mental or physical disability, health status, claims experience, medical history, genetic information, evidence of

insurability or geographic location. *Plans/Part D Sponsors* may not target beneficiaries from higher income areas or state or otherwise imply that plans are available only to seniors rather than to all Medicare beneficiaries. Only SNPs may limit enrollment to dual-eligibles, institutionalized individuals, or individuals with severe or disabling chronic conditions and/or may target items and services to corresponding categories of beneficiaries. Basic services and information must be made available to individuals with disabilities, upon request.

30.*5* - Requirements Pertaining to Non-English Speaking Populations

42 CFR 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 noted in §§ 30.8, 30.9, 30.12, Part D Transition Letter, *and ad-hoc communications regarding payments/reimbursements* available in any language that is the primary language of at least five (5) percent of a *Part D Sponsor's* plan benefit package service area. *The materials in §§ 30.8, 30.9, and 30.12 must be posted on the Plan's/Part D Sponsor's website.*

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

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

30.5.1 – Multi-Language Insert

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

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

Regardless of the 5 percent service area threshold (See 30.7), all plans must include the CMS created Multi-Language Insert with the Summary of Benefits and the ANOC/EOC. *Plans/Part D Sponsors* have the option to incorporate the Multi-Language Insert as part of these materials or to provide as a separate document.

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

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

30.*6* - Required Materials with an Enrollment Form

42 CFR 422.111, 423.128

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

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

30.*7* - Required Materials for New and Renewing Members at Time of Enrollment and Thereafter

42 CFR 422.111, 423.128, 422.2264, 423.2264

- Annual Notice Of Change /Evidence Of Coverage (ANOC/EOC) or EOC as applicable
- *Low Income Subsidy (LIS) Rider (For all Part D Sponsors)*
- Comprehensive formulary or abridged formulary including information on how the beneficiary can obtain a complete formulary (Part D sponsors only)

- Pharmacy directory (For all *Plans/Part D Sponsors* offering a Part D benefit, this is required at time of enrollment, see § 60.4.*1* for additional information)

- Provider directory (For all plan types except PDPs, this is required at time of enrollment, see § 60.4.*2* for additional information)

- Membership Identification Card (required only at time of enrollment and as needed or required by *Plan/Part D Sponsor* post enrollment)

These documents must be provided to all new enrollees no later than ten (10) calendar days from receipt of CMS confirmation of enrollment or by the last day of the month prior to the effective date, whichever is later. *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 Members

42 CFR 422.111, 423.128, 422.2264, 423.2264

Every member must receive the materials noted in 30.9 at the time of enrollment. *Thereafter, Plans/Part D Sponsors may combine the mailing of these materials to members at the same address with the members' consent.* 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 members reside; all enrollees must receive individual membership identification cards.

30.*8* - Hold Time Messages

42 CFR 422.2268(f) and 423.2268(f)

Hold time messages that promote the plan or include benefit information must be submitted in HPMS.

30.*9* – Member Referral Programs

42 CFR 422.2268, 423.2268

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

- A *Plan/Part D Sponsor* can ask for referrals from members, including names and *mailing* addresses, but cannot request phone numbers *or email addresses*. *Plans/Part D Sponsors* may use member provided referral names and *mailing* addresses to solicit potential new members by *conventional* mail only.

- Any solicitation for leads, including letters sent from *Plans/Part D Sponsors* to members, cannot announce that a gift will be offered for a referral.

- Gifts must be of nominal value (refer to §70.1.1- Nominal Gifts).

30.*10* - *Star* Ratings Information from CMS

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

Plans/Part D Sponsors must provide overall *Star* Ratings information to beneficiaries through the standardized *Star* Ratings information document. The *Star* Ratings information document must be distributed with any enrollment form and/or Summary of Benefits. This document must also be available on plan websites.

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

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

Star Ratings are generally issued in October of each year. Plans will be required to use updated *Star* Ratings information within 15 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 new contract year.

30.*10*.1 – Referencing *Star* Ratings in Marketing Materials

- *Plans/Part D Sponsors* may only reference the contract's individual measures in conjunction with its *Overall Star* Rating, *or Part C/D Summary rating* in marketing materials. *Plans/Part D Sponsors* may not use their *Star* Rating in a lower category or measure to imply higher *Overall or Summary Star Ratings* in their marketing materials. For example, a *Plan/Part D Sponsor* which received a 5-*Star Rating* in customer service *may not* promote itself as a "5-*Star* plan," when its Overall Star Rating is actually only 2 Stars. *Plans/Part D Sponsors* must use their Star Ratings in marketing materials in a manner that does not mislead beneficiaries into enrolling in plans based on inaccurate information.

- *MA-PDs that are assigned a Low Performer Icon (LPI) by CMS may not attempt to discredit or refute their LPI status by only showcasing a higher Overall Star Rating. If an organization is an LPI, due to either low Part C or Part D ratings, the organization must clearly indicate their LPI status. For example, an MA-PD that has a 3-star Overall rating, but is an LPI because of their low Part C ratings, may advertise that their Overall star rating is 3, but must also include that for Part C they are an LPI for low Part C or Part D performance. In addition, the organization must also state that their LPI status means that the organization received 2.5 stars or below in either Part C or Part D ratings for the last three years.*

- *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 with low Star Ratings cannot encourage beneficiaries to enroll, based on the argument that if they are dissatisfied with the plans, they can later request SEPs and change to higher rated plans.*

- *Plans/Part D Sponsors with 5-star ratings* may not *conduct activities specifically to market the option* for beneficiaries enrolled in poor performing plans to request a special enrollment period.

- *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 will provide the gold star icon to Plans/Part D Sponsors every fall.*

- *Plans/Part D Sponsors* with one *or more* contracts *with an Overall 5-Star Rating* should not create *or disseminate* materials in a way that implies that all of its contracts achieved this rating. *Materials should list specific contracts with Overall 5-Star Ratings.*

- *Plans/Part D Sponsors may only market their Star Ratings for contracts in that geographic service area as specified in Section 30.1-Limitations on Distribution of Marketing Materials.*

  NOTE: *Plans/Part D Sponsors* are responsible for translating *Star* Ratings information as specified in § 30.7. Translation of *Star* Ratings information will not be considered an alteration of the document.

30.*10*.2 –Plans with an Overall *5*-Star Rating

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

Plans/Part D Sponsors with an overall 5-Star rating may market their ability to enroll beneficiaries through the 5-Star special enrollment period (SEP).

If a *Plan/Part D Sponsor* with an overall 5-Star rating is assessed a rating of less than 5-Stars for the upcoming year, the *Plan/Part D Sponsor* must discontinue marketing for the purposes of accepting enrollments under the 5-Star SEP by November 30 of the current year.

40 - General Marketing Requirements

40.1 - Marketing Material Identification

42 CFR 422.2262, 423.2262, 422.2264, 423.2264

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

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

include approved or accepted statuses only after the material is approved or accepted and not when submitting the material for review.

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

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

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

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

42 CFR 422.2264(e), 423.2264(e)

Non-English or alternate format materials must be given a unique material ID as outlined above. When submitting these materials, *Plans/Part D Sponsors* must designate that they are non-English or alternate format versions in HPMS.

40.2 - Font Size Rule

42 CFR 422.2264, 423.2264

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

Exceptions:

- Television Ads
- ID cards
- Internal tracking numbers
- Logos/logos with taglines
- If a *Plan/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, not how it actually appears on the user's screen.

40.3 - Reference to Studies or Statistical Data

42 CFR 422.2264, 423.2264

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

- *Plans/Part D Sponsors* must provide the study sample size, number of plans surveyed, publication date, and page number in the HPMS marketing material transmittal comments field when uploading the document that includes the reference.

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

- The source and date of the study.
- Information about the *Plan's/Part D Sponsor's* relationship with the entity that conducted the study.
- The study sample size and number of plans surveyed (unless the study that is referenced is a CMS study).
- Reference information, (e.g., publication, date, page number), for CMS studies.

40.4 - Prohibited Terminology/Statements

42 CFR 422.2264, 423.2264, *422.2268(e), 423.2268(e)*

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

Plans/Part D Sponsors may not:

- Claim that they are recommended or endorsed by CMS, Medicare, or the Department of Health & Human Services (DHHS).

- Use absolute superlatives, (e.g., "the best," "highest ranked," "rated number 1"), unless they are substantiated with supporting data provided to CMS as a part of the marketing review process *or unless they are used in logos/taglines*. If the material is submitted via the file & use program, the supporting data must be included, along with the materials that use an absolute superlative.

- Compare their organization/plan(s) to another organization/plan(s) by name unless they have written concurrence from all *Plans/Part D Sponsors* being compared, (e.g., studies or statistical data as described in
§ 40.3). This documentation must be included when the material is submitted in HPMS.

Plans/Part D Sponsors may:

- State that the *Plan/Part D Sponsor* is approved for participation in Medicare programs and/or that it is contracted to administer Medicare benefits.

- Use the term "Medicare-approved" to describe their benefits and services within their marketing materials.

- Use qualified superlatives, (e.g., "one of the best," "among the highest rank").

40.5 - Product Endorsements/Testimonials

42 CFR 422.2264, 423.2264, 422.2268, 423.2268

Product endorsements and testimonials must adhere to the following:

- The speaker must identify the *Plan's/Part D Sponsor's* product by name.

- A Medicare beneficiary may offer endorsement of a *Plan/Part D Sponsor* or promote a specific product, provided the individual is a current member of the plan being endorsed or promoted. If the individual is paid to endorse or promote the plan or product, this must be clearly stated, (e.g., "paid endorsement").

- If an individual, such as an actor, is paid to portray a real or fictitious situation, the ad must clearly state it is a "Paid Actor Portrayal."

- The endorsement or testimonial cannot use any quotes by physicians, health care providers, and/or by Medicare beneficiaries not enrolled in the plan.

- The endorsement or testimonial cannot use negative testimonials about other *Plans/Part D Sponsors*.

40.*6* - Hours of Operation Requirements for Marketing Materials

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

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

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

- The number must be a toll-free number.

- *Plans/Part D Sponsors* must also list the hours of operation for 1-800-MEDICARE any time the 1-800-MEDICARE number or Medicare TTY is listed, (i.e., 24 hours a day/7 days a week).

- Customer service call center hours must be the same for all individuals regardless of whether they speak another language or use assistive devices for communication.

- ID cards are excluded from this requirement.

Refer to § 80.1 for additional guidance.

40.7 - Use of TTY Numbers

Section 501 and Section 504 of the Rehabilitation Act

A TTY number must appear in conjunction with the *Plans/Part D Sponsors* customer service number in the same font size and style as the other phone numbers. *Plans/Part D Sponsors* can either use their own TTY number or State relay services, as long as the number included is accessible from TTY equipment. TTY customer service numbers must be toll-free.

Exceptions:

- Outdoor advertising (ODA) or banner/banner-like ads.
- The Multi-language Insert (Appendix *3*).
- Radio ads *and radio sponsorships*
- In television ads, the TTY number may be a different font size/style than other phone numbers to limit possible confusion. *Plans/Part D Sponsors* may use various techniques to sharpen the differences between TTY and other phone numbers on a television ad (such as using a smaller font size for the TTY number than for the other phone numbers).

40.*8* - Marketing of Multiple Lines of Business

42 CFR 422.2268, 423.2268

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

40.*8*.1 - Multiple Lines of Business - General Information

42 CFR 422.2268, 423.2268

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

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 members receiving the non-renewal notice. These additional materials must be a separate enclosure within the same envelope. Enrollment applications are prohibited from being provided with non-renewal information.

40.*8*.3 - Non-Benefit/Non-Health Service-Providing Third Party Marketing Materials

42 CFR 422.2268, 423.2268

Non-benefit/non-health service providing third party entities are organizations or individuals that supply non-benefit related information to Medicare beneficiaries or a *Plan/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 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 enrollee.

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* members and/or prospective enrollees, *plans must require that the entity* submit its materials to the *Plan/Part D Sponsor* who will ensure compliance with the MMG requirements. See § 50.13.*1*.

40.*9* - Providing Materials in Different Media Types

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

[§1852(c) (1) and §1860D-4(a)(1)(A)]

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). When requesting consent, the *Plan/Part D Sponsor* must specify to the beneficiary the media type and the documents to be sent.

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

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

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

- Inform members of the option and give them the choice to opt-in. If a member no longer wishes to receive plan communications through electronic or portable media, they must be able to opt-out upon request.

- Document each member's choice of media type and (opt-in) election to receive plan communications using that type.

- Have safeguards in place to ensure that member contact information is current, communication materials are delivered and received timely and appropriately, and important materials are identified in a way that members understand their importance.

- Have a process for automatic mailing of hard copies when electronic versions or choice of media types are undeliverable, (e.g., an expired e-mail account).

- Ensure compliance with HIPAA.

40.*10* - Standardization of Plan Name Type

42 CFR 422.2268 (q), 423.2268 (q), section 1851 (*h*)(6) of the 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 the HPMS. *Plans/Part D Sponsors* must include the plan type on all marketing materials when the plan name is mentioned.

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

Plans/Part D Sponsors that have incorporated the plan type at the end of the plan name, (e.g., Gold Plan PFFS), are not required to repeat the plan type in the plan name.

Inclusion of the plan type is not required throughout an entire document. However, plans must include the plan type on the front page or at the beginning of the document. Model documents to which the only modification is the addition of the required plan name type will be considered a model without modification.

50 - Marketing Material Types and Applicable Disclaimers

42 CFR 422.2264, 423.2264

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

50.1 - Federal Contracting Disclaimer

42 CFR 422.2264*(c),* 423.2264*(c)*

All marketing materials, *except for envelopes* must include the statement that the *Plan/Part D Sponsor* contracts with the Federal government.

MA, MA-PD or Cost plans *must use a* contracting statement either in the text of the piece or at the end/bottom of the piece. *The statement should include the legal marketing name, the type of plan and who the contract is with (e.g., Medicare, federal government, state Medicaid program).*

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

50.2 - Disclaimers When Benefits Are Mentioned

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

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

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

50.3 – Disclaimers When Plan Premiums Are Mentioned

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

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

"You must continue to pay your Medicare Part B premium."

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

50.4 – Disclaimer on Availability of Non-English Translations

42 CFR 422.2264, 423.2264

Plans/Part D Sponsors that meet the five (5) percent threshold for language translation (Refer to § 30.7) must place the following alternate language disclaimer on all materials as required.

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

The alternate language disclaimer must be placed in both English and all non-English languages that meet the five (5) percent threshold for the PBPs *related to* the document. The non-English disclaimer must be placed below the English version and in the same font size as the English version.

NOTE: ID cards are excluded from this requirement.

50.5 - SNP Materials

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

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

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

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 - Dual Eligible SNP Materials

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

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

- "[premiums],[co-pays],[co-insurance], and [deductibles] may vary based on *your Medicaid eligibility category and/or* the level of Extra Help you receive. Please contact the plan for further details."

50.7 –Private *Fee-for-*Service Plans

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

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

50.8 –Medicare Medical Savings Accounts (MSAs)

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

- "MSA Plans combine a high deductible Medicare Advantage Plan and a trust or custodial savings account (as defined and/or approved by the IRS). The plan deposits money from Medicare into the account. You can use this money to pay for your health care costs, but only Medicare-covered expenses count toward your deductible. The amount deposited is usually less than your deductible amount, so you generally have to pay out-of-pocket before your coverage begins."

- "Medicare MSA Plans don't cover prescription drugs. If you join a Medicare MSA Plan, you can also join any separate Medicare Prescription Drug Plan."

- "There are additional restrictions to join an MSA plan, and enrollment is generally for a full calendar year unless you meet certain exceptions. Those who disenroll during the calendar year will owe a portion of the account deposit back to the plan. Contact the plan at [insert customer service and TTY] for additional information."

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

42 CFR 422.2268*(n),* 423.2268*(n)*

Plans/Part D Sponsors that choose to enter into co-branding relationships with network providers are required to include the following disclaimer:

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

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

42 CFR 422.2264, *422.2268,* 423.2264, *423.2268*

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

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

50.11 - Disclaimer on Promoting a Nominal Gift

42 CFR 422.2268(b), 423.2268(b)

- *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 422.2264, 423.2264

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

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

50.13 - Disclaimer When Using Third Party Materials

42 CFR 422.2264, 423.2264

CMS does not review materials developed by a 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

Any materials *from a third party* providing information on a subset of plan options must prominently display the following disclaimer on all materials.

- "This is not a complete listing of plans available in your service area. For a complete listing please contact 1-800-MEDICARE (TTY users should call 1-877-486-2048), 24 hours a day/7 days a week or consult www.medicare.gov."

This disclaimer must be prominently displayed on all material (or on each webpage) that lists, compares, or names available plans.

Plans/Part D Sponsors are responsible for ensuring that non-benefit/service providing third-party entities comply with all MMG requirements prior to distributing materials to their membership. For further details on what CMS considers a non-benefit/non-health service providing third-party entity, please refer to § 40.11.3.

50.14 - Disclaimer When Referencing Plan Ratings Information

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

> "*Plan performance Star Ratings are based on 5 Stars.* Plan performance Star Ratings are assessed each year and may change from one year to the next."

50.15 – Pharmacy Directory Disclaimers

• If a directory is a subset of a service area, Part D sponsors must *advise members that*: *"This directory is for <geographic area>;" that they can either visit the website or call the plan for additional information; and that the contact information appears on the bottom of every page.*

• If a *Part D Sponsor* lists pharmacies in its network but outside the service area, Part D sponsors must *advise members that*: *"We also list pharmacies that are in our network but are outside <geographic area>;" that they can*

either visit the website or call the plan for additional information; and that the contact information appears on the bottom of every page.

50.16 – Mailing Statements

42 CFR 422.2272(b), 423.2272(b)

In order to ensure that beneficiaries can quickly and easily identify the contents of a *Plan's/Part D Sponsor's* mailing, all *Plans/Part D Sponsors* that mail information to prospective or current Medicare beneficiaries must prominently display one of the following four statements on the front of the envelope or if no envelope is being sent, the mailing itself. *Plans/Part D Sponsors* may meet this requirement through the use of ink stamps or stickers, in lieu of pre-printed statements. Any delegated or sub-contracted entities and downstream entities that conduct mailings on behalf of a *Plan/Part D Sponsor* must comply with this requirement.

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

All mailings should include one of these four mailing statements. If a mailing is not advertising or a health and wellness mailing, but is related to an enrollee's plan, *Plans/Part D Sponsors* should categorize it as a plan information mailing. However, if the mailing contains non-health or non-plan related information (refer to § 160.2 for examples), a *Plan/Part D Sponsor* should use the "non- health or non-plan related information" mailing statement. *Plans/Part D Sponsors* may not modify these mailing statements and must use them verbatim.

In addition, *Plans/Part D Sponsors* must ensure that their plan name or logo is included on every envelope to current and prospective enrollees (either on the front envelope or on the mailing when no envelope accompanies the mailer).

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

NOTE: *Plans/Part D Sponsors* are not required to include the material ID on envelopes; however all envelopes must be submitted with an associated marketing material ID number.

50.17 – Other Formulary Documents

The following disclaimer must be displayed prominently on the cover of *other formulary* documents *referenced in section 60.5.4*: "This is not a complete list of drugs covered by our plan. For a complete listing, please call <Customer Service Phone and TTY Numbers/> or visit <website address>".

60 - Required Documents

60.1 - Summary of Benefits (SB)

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

The SB is a standardized document that should be generated via HPMS. *Plans/Part D Sponsors* are required to include the SB when providing an enrollment form and also upon request. Additionally, *Plans/Part D Sponsors* must provide the multi-language insert any time they distribute an SB (see 30.7.*1*).

The SB allows beneficiaries to more easily compare the benefits offered by different *Plans/Part D Sponsors* and includes the following:

- Section (I): An introduction and the beneficiary information section, informing prospective enrollees of important aspects of enrolling in the plan.
- Section (II): A benefit comparison matrix, which is an output report of the *Part D Sponsor's* PBP and Premium Table. *Part D Sponsors* with identical benefits offered in different regions may insert a table indicating the premium in each region.
- Section (III): An optional free-form text area. This section is limited to six pages and can be used by plans to further describe special features of the program.
- Section (IV) or Medicaid Benefits: D-SNPs must provide each prospective enrollee prior to enrollment with a comprehensive written statement that describes:

- The benefits that the individual is entitled to under Title XIX (Medicaid);
- The cost-sharing protections that the individual is entitled to under Title XIX (Medicaid);
- The description of the benefits and cost-sharing protections that are covered under the D-SNP.

Plans/Part D Sponsors must ensure that the language for sections I and II are identical to the SB report in HPMS. Any deviation from this language, outside of an approved hard copy change or global hard copy change, will make the material non-compliant. Deviations include, but are not limited to, insertion of footnotes, plan specific clarifications, or format alterations, except as indicated in the SB instructions. All sections of the SB must be submitted to CMS as one document under the File & Use process. 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 within Section II of the benefit comparison matrix. Since the PBP will only print Sections I and II of the SB 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 Section I (introduction) to accurately reflect the plans that have been added to Section II.

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

60.2 - ID Card Requirements

42 CFR 417.42*8*, 422.111(i), 423.120(c)

All *Plans/Part D Sponsors* must issue and reissue (as appropriate) member identification cards that members may use to access covered services under the plan.

All Plans/Part D Sponsors must obtain a CMS-issued Health Plan Identification Number (HPID). (Note: As of date, CMS has not issued HPIDs. Therefore, implementation of the machine-readable technology requirements (magnetic strip or bar code) in the Workgroup for Electronic Data Interchange (WEDI) and National Council for Prescription Drug Program (NCPDP) standards will be delayed until (and coordinated with) implementation of the HPID).

For questions related to the HPID go to the [INSERT OESS WEBPAGE TITLE]<link>.

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

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

ID cards may be printed using a font size equivalent to the NCPDP or WEDI standard.

Combination health and drug plan ID cards must follow the WEDI standard and must include the required information in 6*0*.2.1 and 6*0*.2.2 below.

ID cards are not required to include:

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

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

60.2.1 – Health Plan ID Card Requirements

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

Health plan ID cards must also include:

- The *Plan* website address.

- The *Plan's* customer service number.
- The phrase "Medicare limiting charges apply" (on PPO and PFFS cards only).

60.2.2 – Part D *Sponsor* ID Card Requirements

Other than any exceptions cited in section 60.2, the Part D *Sponsor* member identification card must meet the most recent version of the NCPDP's "Pharmacy and/or Combination ID Card" standard. This standard is based on the American National Standards Institute ANSI INCITS 284-1997 standard titled Identification Card – Health Care Identification Cards.

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

60.3 - Reserved

60.4 - Directories

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

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

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

NOTE: Employer/Union-only Group Waiver Plans (EGWP) can direct members to their employer for information on the available providers. Employer/Union-only Group Waiver Plans (EGWP) must comply with requirements to mail directories and post directories on their plan website.

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

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

See § 100 for additional website requirements.

60.4.1 - Pharmacy Directories

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

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

Part D sponsors must advise beneficiaries that they generally must use network pharmacies to receive plan coverage. If the network consists of preferred and non-preferred pharmacies, the sponsor must identify the preferred pharmacies and indicate that members may save on cost-sharing at preferred pharmacies. For more information, visit section 50.9 in the Prescription Drug Benefit Manual Chapter 5: Benefits and Beneficiary Protections (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/MemoPDBManualChapter5_093011.pdf).

60.4.1.1 – Information about Pharmacies

The pharmacy directory *must*:

- *Provide* pharmacy name, address, phone number *for all network pharmacies except:*
    - *For chain pharmacies, sponsors have the option to provide a toll-free customer service number and a TTY number that a member 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 members to call, then plans must list each chain pharmacy location and phone number in the directory. If the chain pharmacy does not have a TTY number, Part D Sponsors are instructed to list the TRS Relay number 711. Part D Sponsors should not list their own customer service number as a pharmacy phone number or TTY number.*
- *Identify type of pharmacy (e.g., retail, mail order, long-term care, home infusion, I/T/U).*
- *Identify* which *pharmacies provide* an extended day supply of medications.
- Part D sponsors may indicate which of their network pharmacies support e-prescribing in their pharmacy directories. Model directories that include e-prescribing information will still be considered model.

60.4.2 - Provider Directories

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

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

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

Plans/Part D Sponsors may publish separate PCP and specialty directories provided both directories are given to enrollees at the time of enrollment and every three years from the enrollment date.

60.5 - Formulary and Formulary Change Notice Requirements

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

Part D sponsors must provide a list of drugs, known as a formulary, to *members* at the time of enrollment and at least annually thereafter. *While the print version of the formulary may be abridged, each Plan/Part D Sponsor must* provide *a comprehensive formulary on its website. See the Prescription Drug Benefit Manual, Chapter 6 for program guidance regarding formularies, change notices, and utilization management (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf).*

Part D sponsors are responsible for ensuring 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 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 Prescription Drug Manual, Chapter 6, § 30.3 (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf).

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 member through the end of the contract year.

60.5.1 - Abridged Formulary

42 CFR 423.128

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

- Plan Name on cover page
- "<Year> Formulary (List of Covered Drugs)" on cover page
- "PLEASE READ: THIS DOCUMENT CONTAINS INFORMATION ABOUT THE DRUGS WE COVER IN THIS PLAN" on cover page
- *Advise members that the document includes a partial list of drugs; that members can visit the website or call the plan for a complete list of covered drugs; and that contact information appears on the bottom of every page.*
- The following statement: "Note to existing members: This formulary changes *yearly. If you belonged to the plan in [the year prior to the contract 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 plan's formulary document.
- The following statement: "<Part D Plan Name> covers both brand name drugs and generic drugs. A generic drug is approved by the FDA as having the same active ingredient as the brand name drug. Generally, generic drugs cost less than brand name drugs.
- A statement describing the Part D plan's general utilization management procedures.

- *A statement that if a drug is not on the formulary, members may contact the plan 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 plan's formulary, utilization management tools or tiered cost sharing

- A description of the plan's drug transition policy.

- *A statement that members may contact the plan for additional information or questions on the formulary.*

- A chart (the approved CMS formulary) of covered drugs organized by therapeutic category that includes at least two covered drugs for each therapeutic class. Exceptions to this include when only one drug exists in the category or class or in the case where two drugs exist in the category or class, and one is clinically superior to the other. The category or class names must be the same as those found on the CMS approved Part D plan formulary.

  NOTE: While Part D plans must ensure that at least two drugs per therapeutic class are included within the abridged formulary, Part D plans have the option to include the therapeutic classes as subheadings within the abridged formulary, as this level of detail may be confusing for beneficiaries. The row of the chart must include at least the three items described below.

  - Drug Name: We suggest capitalizing brand name drugs, (e.g., LIPITOR) and listing generic drugs in lowercase italics, (e.g., penicillin). Part D plans may include the generic name of a drug next to the brand name of the drug. The abridged formulary may only consist of drugs included on the CMS approved HPMS formulary. Formulary drug enhancements described in § 60.5 may not be included in the abridged formulary document.

  - Tier Placement: Part D plans that provide different levels of coverage for drugs depending on their tier should include a column indicating the drug's tier placement and the corresponding tier label description (e.g., Generic or Preferred Brand), from the approved PBP. Part D plans may also choose to include a column providing the co-payment or co-insurance amount for each tier.

  - Utilization Management (UM): Part D plans must indicate any applicable UM tools (e.g., prior authorization, step therapy, and

quantity limit restrictions), for the drug. A description of the indicator used to describe the UM tools must be provided somewhere within the document (e.g., in footnotes). For example, a Part D plan may choose to designate a prior authorization on a drug by placing an asterisk next to the name of the drug.

- An index listing drugs in alphabetical order that directs the reader to the page containing complete information for that drug, (e.g., name, tier placement, and utilization management strategy); this is because many beneficiaries may only know the name of their prescription and not its therapeutic class.
- *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).

60.5.2 - Comprehensive Formulary

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

The comprehensive formulary must include the same information provided within the abridged formulary document, except that the comprehensive formulary must include the entire list of drugs covered by the Part D plan (*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 § 60.5.

- *NOTE: Every beneficiary must be able to tell by examining the 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.*

60.5.3 - Changes to Printed Formularies

42 CFR 423.128(a)-(c)

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

Part D sponsors may make any necessary formulary changes via errata sheets mailed to affected members. While Part D sponsors retain the flexibility to utilize other processes for notifying beneficiaries of non-maintenance changes to their printed formularies, CMS expects Part D sponsors to send out errata sheets with formulary changes no less than monthly to the extent that any negative formulary changes have occurred and that affected members will receive a hard copy of such changes (website updates alone will not suffice). Errata sheets must include a statement explaining that the plan will continue to cover the drugs in question for enrollees taking the drug at the time of change for the remainder of the plan year as long as the drug continues to be medically necessary and prescribed by the member's physician and was not removed for safety reasons. Refer to the Prescription Drug Manual, Chapter 6, §§ 30.3.3.3 and 30.3.4.1. This requirement does not extend to mid-year maintenance changes defined in § 30.3.3.2 *(http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf)*. Changes to previously printed formularies resulting from mid-year maintenance changes may be made at the time of the next printing. This is not a substitute for the required advance 60 *days' notice* to affected beneficiaries.

60.5.4 - Other Formulary Documents

42 CFR 423.128(b)(4)

In addition to comprehensive and abridged formularies, Part D plans may choose to develop a formulary that lists all of their preferred drugs or is tailored to individuals with specific chronic conditions, as long as these items supplement the two required documents rather than replace them *and include the disclaimer in section 50.17.*

60.5.5 - Provision of Notice to Beneficiaries Regarding Formulary Changes

42 CFR 423.120(b)(5)

Part D plans must provide at least sixty (60) *days' notice* to beneficiaries before removing a Part D drug from the Part D plan's formulary, (e.g., adding prior authorization, quantity limits, step therapy or other restrictions on a drug), or moving a drug to a higher cost-sharing tier. *Sixty day notice must be provided in writing unless a beneficiary has affirmatively elected to receive electronic notice. In such instances,* Part D plans can determine the most effective means by which to communicate *the 60-day notice of* formulary change information to beneficiaries, including electronic means. Part D sponsors should refer to *Prescription Drug Manual, Chapter 6*, § 30.3.4 *(http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf*).

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*, § 30.3.4.2 of *(http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf).*

60.6 - Part D Explanation of Benefits

42 CFR 423.128(e)

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

If a *Part D Sponsor* chooses to develop a non-model EOB, the EOB must contain all information and follow all instructions within the CMS model.

> NOTE: An EOB does not need to be generated by the *Part D Sponsor* when retroactive changes apply to prior benefit year prescription fills. For example, a plan's final EOB for CY *2013* must be sent in January *2014*, for December 2011 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 member receipt by September 30 of each year. New Enrollees with an effective date of October 1, November 1, or December 1, should receive both an EOC for the current contract year and an ANOC/EOC for the upcoming contract year. New enrollees with an effective date of January 1 or later must receive an EOC for the contract year of coverage. *Additional materials may not be included in the ANOC/EOC mailing unless otherwise specified.* Standalone EOC's do not need to be resubmitted in HPMS.

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

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

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

To ensure that *Plans/Part D Sponsors* are mailing their ANOC/EOC timely, *Plans/Part D Sponsors* must indicate the actual mail date in HPMS within three (3) days of mailing. *Plans/Part D Sponsors* that mail in waves should enter the actual date for each wave. For instructions on meeting this requirement, refer to the *Update Material Link/Function* section of the Marketing Review Users Guide in HPMS.

Plans/Part D Sponsors must use the standardized ANOC/EOC errata model to correct any errors and must submit the errata model for review via HPMS. *Plans/Part D Sponsors* must ensure corrected versions of the EOC are on

their websites. *Plans/Part D Sponsors* are not required to post the ANOC or the ANOC/EOC errata model on websites.

60.8 - Mid-Year Changes Requiring Enrollee Notification

42 CFR 422.111(d)(3)

When a National Coverage Determination (NCD) or legislative benefit change takes effect mid-year, *Plans/Part D Sponsors* must ensure access to the NCD item or service by furnishing or arranging for the service as of the effective date of the NCD or legislative benefit change. This requirement is applicable regardless of whether provider payment is the responsibility of the plan or Original Medicare, as described in detail in the Medicare Managed Care Manual, Pub 100-16, Chapter 4, section 90.4 (General Rules for NCDs). All NCDs are effective on the date the decision memorandum is released, (i.e., the same as the date it is posted to the National Coverage Analysis page of the Medicare Coverage Center website at http://www.cms.gov/mcd/index_list.asp?list_type=nca). The *Plans/Part D Sponsors* is required to notify all enrollees of the change in coverage. If payment for the covered service is the responsibility of Original Medicare, the enrollee must be told that he or she can receive this service from any Medicare provider. Notifications must occur within 30 days of the release date of the NCD or legislative benefit change.

The *Plans/Part D Sponsors* may use a variety of mechanisms to inform enrollees of the change in coverage. At a minimum, the notice must be provided on the plan website within 30 days, with subsequent publication in the next plan newsletter or other mass mailing not specifically dedicated to the NCD notification. Alternatively, *Plans/Part D Sponsors* may choose to provide this information to enrollees in a targeted way, such as via email or one-time mailings specific to this issue. NCD communications do not need to be submitted in HPMS.

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

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

70.*1* - Promotional Activities

42 CFR 422.2268, 423.2268

Generally, promotional activities *include nominal gifts and* are designed to attract the attention of prospective members and/or encourage retention of current members. In addition to the guidance on nominal gifts (refer to 70.1.*1*), any promotional activities or items offered by *Plans/Part D Sponsors*:

- Must be worth $15 (*based on the retail value of the item*) or less with a maximum aggregate of $50 per person, per year,
- Must be offered to all people regardless of enrollment and without discrimination;
- Must not be items that are considered a health benefit, (e.g., a free checkup);
- Must not inappropriately influence the beneficiary's selection of a provider, practitioner, or supplier of any item or service;
- Must not be tied directly or indirectly to the provision of any other covered item or service.

  Note: *Plans/Part D Sponsors* must track and document items given to current members. *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(b), 423.2268(b)

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

The following rules must be followed when providing gifts:

- If a nominal gift is one large gift that is enjoyed by all in attendance (e.g., a concert), the total retail *value* must be $15 or less when it is divided by the estimated attendance. For planning purposes, anticipated attendance may be used, but must be based on venue size, response rate, or advertisement circulation.
- Nominal gifts may not be in the form of cash or other monetary rebates. Cash gifts are prohibited even if their worth is less than $15.

Cash gifts include charitable contributions made on behalf of potential enrollees, and those gift certificates and gift cards that can be readily converted to cash, regardless of dollar amount.

NOTE: Plans/Part D Sponsors should refer to the Office of Inspector General's website regarding advisory opinions on gift cards.

70.2 - Rewards and Incentives

42 CFR 422.2268, 423.2268

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

Reward and incentive items must:

- Be offered in connection with the whole service, (e.g., a *Plan/Part D Sponsor* may offer a reward for participating in the smoking cessation program but not offer multiple awards for attending each smoking cessation class.);
- Be offered to all eligible members without discrimination;
- Have a monetary cap not to exceed $15 per reward item (based on the retail value of the item);
- Be tracked and documented during the contract year;
- Comply with all relevant fraud and abuse laws, including, when applicable, the anti-kickback statute and civil monetary penalty prohibiting inducements to beneficiaries; and

Additionally, reward and incentive items cannot:

- Be items that are considered a health benefit, (e.g., a free checkup);
- Be items that consist of lowering or waiving co-pays;
- Be offered in the form of cash or other monetary rebates;
- Be used to target potential enrollees (e.g., used in pre-enrollment advertising, marketing, or promotion of the plan);

- Be structured to steer enrollees to particular providers, practitioners, or suppliers; and
- Be tied directly or indirectly to the provision of any other covered item or service.

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

- Main Coverage Center page - https://www.cms.gov/center/coverage.asp
- Sign-up for the coverage listserv - https://www.cms.gov/InfoExchange/03_listserv.asp#TopOfPage
- Program Transmittals page - http://www.cms.gov/Transmittals/

70.*3* - Exclusion of Meals as a Nominal Gift

42 CFR 422.2268(p), 423.2268(p)

Plans/Part D Sponsors may not provide meals (or have meals subsidized) at sales/marketing events.

Plans/Part D Sponsors are, however, allowed to provide refreshments and light snacks. *Plans/Part D Sponsors* must use their best judgment on the appropriateness of food products provided and must ensure that items provided could not be reasonably considered a meal and/or that multiple items are not being "bundled" and provided as if a meal.

Meals may be provided at educational events, provided the event meets CMS' strict definition of an educational event, and complies with the nominal gift requirement in § 70.1.

70.*4* - Unsolicited E-mail Policy

42 CFR 422.2268(d) 423.2268(d)

A *Plan/Part D Sponsor* may not send e-mails unless an individual has agreed to receive those e-mails. Furthermore:

- *Plans/Part D Sponsors* are prohibited from renting and purchasing e-mail lists to distribute information about MA, PDP, or section 1876 cost plans.

- *Plans/Part D Sponsors* may not e-mail individuals at e-mail addresses obtained through friends or referrals.
- *Plans/Part D Sponsors* must provide an opt-out process to no longer receive e-mail communications.

70.*5* - Marketing through Unsolicited Contacts

42 CFR 422.2268(d), 423.2268(d)

In general, *Plans/Part D Sponsors* may not market through unsolicited contacts; including but not limited to:

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

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

The prohibition on marketing through unsolicited contacts does not extend to mail and other print media (e.g., advertisements, direct mail).

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

70.*6* - Telephonic Contact

42 CFR 422.2268(d), 423.2268(d)

Agents may contact their own clients and *Plans/Part D Sponsors* may contact current members at *any time* to discuss plan business. Prohibited telephonic activities include, but are not limited to, the following:

- Bait-and-switch strategies - making unsolicited calls about other business as a means of generating leads for Medicare plans.

- Calls based on referrals. If an individual would like to refer a friend or relative to an agent or *Plan/Part D Sponsor*, the agent or *Plan/Part D Sponsor* may provide contact information such as a business card that the individual may give to the friend or family member. In all cases, a referred individual needs to contact the plan or agent/broker directly.

- Calls to former members who have disenrolled, or to current members who are in the process of voluntarily disenrolling (except as permitted below), to market plans or products. Members who are voluntarily disenrolling from a plan should not be contacted for sales purposes or be asked to consent in any format to further sales contacts.

- Calls to beneficiaries who attended a sales event, unless the beneficiary gave express permission at the event for a follow-up call (including documentation of permission to be contacted).

- Calls to beneficiaries to confirm receipt of mailed information, except as permitted below.

Plans/Part D Sponsors may do the following:

- Contact beneficiaries who submit enrollment applications to conduct quality control and agent/broker oversight activities.

- Contact their members or use third-parties to contact their current members. Examples of allowed contacts include, but are not limited to, calls to members aging-in to Medicare from commercial products offered by the same sponsoring organization and calls to an organization's existing Medicaid plan members to talk about its Medicare products.

- Contact members to promote other *Medicare* plan types, (e.g., sponsors may contact their PDP members to promote their MA-PD offerings; *sponsors that are also Medigap issuers may market their MA, PDP, or cost plan products to their Medigap customers*), and discuss plan benefits.

- Contact their members to discuss educational events.

- Contact their members to conduct normal business related to enrollment in the plan, including calls to members who have been involuntarily disenrolled to resolve eligibility issues.

- Call former members after the disenrollment effective date to conduct disenrollment surveys for quality improvement purposes.

Disenrollment surveys may be done by phone or sent by mail, but neither calls, nor mailings, may include sales or marketing information.

- Under limited circumstances and subject to advance approval from the appropriate CMS Regional Office, call LIS-eligible members that a plan is prospectively losing due to reassignment to encourage them to remain enrolled in their current plan.

- Call individuals who have expressly given permission for a plan or sales agent to contact them, for example, by filling out a BRC or asking a customer service representative (CSR) to have an agent contact them. This permission applies only to the entity from which the individual requested contact, for the duration of that transaction, for the scope of product, (e.g., MA-PD plan or PDP), previously discussed or indicated in the reply card.

- Return phone calls or messages, as these are not unsolicited.

- Contact their members via an automated telephone notification to inform them about general information such as the AEP dates, availability of flu shots, upcoming plan changes, and other important information.

70.7 - Outbound Enrollment and Verification Requirements

42 CFR 422.2272(b), 423.2272(b)

To ensure that individuals requesting enrollment understand the plan rules, all Plans/Part D Sponsors are required to conduct outbound enrollment and verification (OEV) calls for *enrollment requests in which an independent or employed agent/broker provided plan-specific information to the individual, thus influencing the individual's plan choice and/or assisting in a subsequent enrollment request*. It is important for the *Plan's/Part D Sponsor's* sales staff to obtain from the applicant the best phone number to be used for verification and to provide a description of the enrollment verification process to the applicant during the application process.

OEV calls must be made to the applicant after the sale has occurred; they cannot be made at the point of sale. The *Plan/Part D Sponsor* must ensure that the verification calls are not conducted by sales agents and that sales agents are not physically present with the applicant at the time of the verification call. *Plans/Part D Sponsors* may not use automated calling technologies to conduct these outbound calls; CMS expects OEV calls to be interactive.

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

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

Plans/Part D Sponsors must make a minimum of three documented attempts, *each occurring on different days,* to contact the applicant by telephone within fifteen (15) calendar days of receipt of the *enrollment request*; the first two attempts must be made within the first 10 days. If the enrollment *request* is incomplete *upon initial receipt, Plans/Part D Sponsors are expected to* concurrently conduct the OEV process while *attempting to* obtain the information needed to complete the *enrollment request*.

Plans/Part D Sponsors must not delay processing the enrollment request (including, but not limited to, activation of benefits and submission of enrollment request data to CMS) while completing the OEV process. If the sponsor does not have all the information required to complete the enrollment process at the time of the OEV call, the sponsor should obtain that information during the call. If the sponsor makes a determination to deny an enrollment request prior to completing the OEV process, the sponsor must discontinue the OEV process. If the sponsor receives a TRR from CMS rejecting the enrollment prior to completing the OEV process, the sponsor must suspend the OEV process but must resume if the sponsor determines the rejection to be erroneous, such that the enrollment will be resubmitted to CMS.

Plans/Part D Sponsors that *are unable to* successfully *complete the outbound verification* on the second attempt must send the applicant an enrollment verification letter, in addition to *any other required enrollment notice, such as enrollment acknowledgement and confirmation notices, and in addition to* making the third documented outbound verification call attempt within the 15 day timeframe. *CMS expects that both the telephone script and the enrollment verification letter will inform beneficiaries that they must notify the Part D Sponsor of their intent to cancel the processing of their enrollment within seven (7) calendar days from the date of the letter or by the last day of the month in which the enrollment request was received, whichever is later. For AEP enrollment requests, the script and the enrollment verification letter will inform beneficiaries that they must notify the Part D Sponsor of their intent to cancel the processing of their enrollment by December 31.*

70.8 - 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 may not include any sales activities such as the distribution of marketing materials or the distribution or collection of plan applications. Educational events must be explicitly advertised as "educational," otherwise, they will be considered by CMS as sales/marketing events.

The intent of this guidance is not to preclude *Plans/Plan Sponsors from* educating beneficiaries about their products; rather, it is to ensure that events that are advertised as "educational" comply with CMS' requirements. More specifically, *Plans/Plan Sponsors may* provide education at a sales or marketing event, but may not market or sell at an educational event.

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

The following are examples of acceptable materials and activities by *Plans/Plan Sponsors or* their representatives at an educational event:

- A banner with the plan name and/or logo displayed.
- Promotional items, including those with plan name, logo, and toll-free customer service number and/or website. Promotional items must be free of benefit information and consistent with CMS' definition of nominal gift.
- Respond to questions asked at an educational event.

Plans/Plan Sponsors or their representatives may not:

- Discuss plan-specific premiums and/or benefits.
- Distribute plan specific materials.

- Distribute or display business reply cards, scope of appointment forms, enrollment forms, or sign-up sheets.

- Set up individual sales appointments or get permission for an outbound call to the beneficiary.

- Attach business cards or plan/agent contact information to educational materials, unless requested by the beneficiary.

- Advertise an educational event and then have a marketing/sales event immediately following in the same general location, (e.g., same hotel).

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

70.*9* - Marketing/Sales Events

42 CFR 422.2268, 423.2268

Marketing/sales events are events designed to steer, or attempt to steer, potential enrollees toward a plan or limited set of plans. At marketing/sales events, plan representatives may discuss plan specific information and collect applications.

There are two main types of marketing/sales events – formal and informal.

Formal marketing/sales events are typically structured in an audience/presenter style with a sales person or plan representative formally providing specific *Plan/Part D Sponsor* information via a presentation on the products being offered.

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

- *Plans/Plan Sponsors must* submit all sales scripts and presentations for approval to CMS prior to their use during the marketing/sales event. *This includes talking points and/or anticipated questions and answers.*

At a marketing/sales event, *Plans/Plan Sponsors may* not:

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

- Require beneficiaries to provide any contact information as a prerequisite for attending the event. This includes requiring an email address or any other contact information as a condition to RSVP for an event online or through mail. Plans should clearly indicate on any sign-in sheets that completion of any contact information is optional.

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

70.*9*.1 – Notifying CMS of Scheduled Marketing Events

42 CFR 422.2268, 423.2268

Plans/Plan 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.

Cancellations - Notification of cancelled sales events should be made, whenever possible, more than forty-eight (48) hours prior to the originally scheduled date and time of the event. *Plans/Plan Sponsors should* notify beneficiaries of event cancellations according to the following requirements. (The method used to notify beneficiaries of the cancellation may vary depending on the individual plan's circumstances.)

1. If a sales event is cancelled less than forty-eight (48) hours before its originally scheduled date and time, the *Plan/Part D Sponsor* must:

    - Cancel the event in HPMS.

    - Ensure a representative of the *Plan/Part D Sponsor* is present at the site of the cancelled sales event, at the time that the event was scheduled to occur, to inform attendees of the cancellation and distribute information about the *Plan/Part D Sponsor*. The representative should remain on site at least 15 minutes after the scheduled start of the event.

      NOTE: If the event was cancelled due to inclement weather, a representative is not required to be present at the site.

2. If a sales event is cancelled more than forty-eight (48) hours before the originally scheduled date and time, the *Plan/Part D Sponsor* must:

    - Cancel the event in HPMS.
    - Notify beneficiaries of the cancellation by the same means the *Plan/Part D Sponsor* used to advertise the event. A representative is not required to be present at the site.

Example of reasonable notification:

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

70.*9*.2 - Personal/Individual Marketing Appointments

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

Personal/individual marketing appointments typically take place in the Medicare beneficiary's home; however, these appointments can also take place in other venues such as a library or coffee shop. Appointments must follow the scope of appointment guidance (See § 70.10.3).

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

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

- Discuss plan options that were NOT agreed to by the Medicare beneficiary.
- Market non-health care related products (such as annuities or life insurance).
- Ask a beneficiary for referrals.
- Solicit/accept an enrollment request (application) for a January 1st effective date prior to the start of the Annual Enrollment Period (AEP) unless the beneficiary is entitled to another enrollment period.

70.*9*.3 - Scope of Appointment

42 CFR 422.2268(g) and (h), 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 face-to-face individual meeting. The Plan/Part D Sponsor must* document the scope before the appointment. *Distinct lines of plan business include MA and PDP products. If a Plan/Part D Sponsor would like to discuss additional products during the appointment that the beneficiary did not agree to, they must document it 48-hours in advance, when practicable. If it is not practicable and the beneficiary requests to discuss other products, the Plan/Part D Sponsor must document a second scope of appointment for the new product type to continue the marketing appointment.*

To further clarify the requirements around documentation:

- The documentation can be in writing, in the form of a signed agreement by the beneficiary, or a recorded oral agreement. *Plans/Part D Sponsors* are allowed and encouraged to use a variety of technological means to fulfill the scope of appointment requirement, including conference calls, fax machines, designated recording line, pre-paid envelopes, and e-mail, etc.

- A beneficiary may set a scope of appointment at a marketing/sales event for a future appointment.

NOTE: All business reply cards (BRC) used for documenting beneficiary scope of appointment or agreement to be contacted must be submitted to CMS for review and approval. Additionally, *Plans/Part D Sponsors* should include a statement on the BRC informing the beneficiary that a sales person may call as a result of their returning a BRC.

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

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

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

In instances where a beneficiary visits a plan or an agent/broker office on his/her own accord, the *Plan/Part D Sponsor* or agent/broker must

document the scope of appointment prior to discussing MA, PDP, or cost plans.

70.*10* - PFFS Plan Provider Education and Outreach Programs

42 CFR 422.114(a)(1)

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

70.*10*.1 - PFFS Plan Terms and Conditions of Payment Contact and Website Fields in HPMS

42 CFR 422.114

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

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

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

70.11 - Marketing in the Health Care Setting

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

Plans/Part D Sponsors and providers who they have a relationship with, (contract or otherwise), that assist beneficiaries with plan selection should

ensure that provider assistance results in plan selection that is always in the best interest of the beneficiary. Providers that have entered into co-branding relationships with *Plans/Part D Sponsors* must also follow these guidelines.

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

Plans/Part D Sponsors are prohibited from conducting sales presentations, distributing and accepting enrollment applications, and soliciting Medicare beneficiaries in areas where patients primarily intend to receive health care services or are waiting to receive health care services. These restricted areas generally include, but are not limited to, waiting rooms, exam rooms, hospital patient rooms, dialysis center treatment areas (where patients interact with their clinical team and receive treatment), and pharmacy counter areas (where patients interact with pharmacy providers and obtain medications). The prohibition against conducting marketing activities in health care settings extends to activities planned in health care settings outside of normal business hours.

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. Providers are permitted to make available and/or distribute plan marketing materials as long as the provider and/or the facilities distributes or makes available *Plan/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, if a provider agrees to make available and/or distribute plan marketing materials they should do so knowing they must accept future requests from other *Plans/Part D Sponsors* with which they participate. Providers are also permitted to display posters or other materials in common areas such as the provider's waiting room. Additionally, long-term care facilities are permitted to provide materials in admission packets announcing all plan contractual relationships.

Long term care facility staff are permitted to provide residents that meet the I-SNP criteria an explanatory brochure for each I-SNP with which the facility contracts. The brochure can explain about the qualification criteria and the benefits of being enrolled in an I-SNP. The brochure may have a reply card

or telephone number for the resident or responsible party to call to agree to a meeting or request additional information.

70.*11*.1 - Provider-Based Activities

42 CFR 422.2268(j), 423.2268(j)

CMS is concerned with provider marketing activities *because*:

- Providers may not be fully aware of all plan benefits and costs.
- Providers may confuse the beneficiary if the provider is perceived as acting as an agent of the plan versus acting as the beneficiary's provider.
- Providers may face conflicting incentives when acting as a *Plan/Part D Sponsor* representative.

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

- Offer sales/appointment forms.
- Accept Medicare enrollment applications.
- Make phone calls or direct, urge or attempt to persuade beneficiaries to enroll in a specific plan based on financial or any other interests of the provider.
- Mail marketing materials on behalf of *Plans/Part D Sponsors*.
- Offer anything of value to induce plan enrollees to select them as their provider.
- Offer inducements to persuade beneficiaries to enroll in a particular plan or organization.
- Conduct health screening as a marketing activity.
- Accept compensation directly or indirectly from the plan for beneficiary enrollment activities.

- Distribute materials/applications within an exam room setting.

Plans/Part D Sponsors may allow contracted providers to:

- Provide the names of *Plans/Part D Sponsors* with which they contract and/or participate (See § 70.12.2 for additional information on affiliation).

- Provide information and assistance in applying for the LIS.

- Make available and/or distribute plan marketing materials.

- Refer their patients to other sources of information, such as SHIPs, plan marketing representatives, their State Medicaid Office, local Social Security Office, CMS' website at http://www.medicare.gov/ or 1-800-MEDICARE.

- Share information with patients from CMS' website, including the "Medicare and You" Handbook or "Medicare Options Compare" (from http://www.medicare.gov), or other documents that were written by or previously approved by CMS.

70.*11*.2 - Provider Affiliation Information

42 CFR 422.2268, 423.2268

Plans/Part D Sponsors may allow contracted providers to announce new or continuing affiliations for specific *Plans/Part D Sponsors* through general advertising, (e.g., radio, television, websites). New affiliation announcements are for those providers that have entered into a new contractual relationship with the *Plan/Part D Sponsor. Plans may allow contracted providers to* make new affiliation announcements within the first 30 days of the new contract agreement. *Plans may allow contracted providers to communicate once through direct mail, e-mail, or phone an* announcement to patients of a new affiliation which names only one *Plans must make sure that contracted providers* include a list of all plans with which the provider contracts *in additional direct mail and\or email communications.*

Any affiliation communication materials that describe plans in any way, (e.g., benefits, formularies), must be approved by CMS *and must include the appropriate disclaimer (refer to section 50).* Multiple *Plans/Part D Sponsors* can either have one *Plan/Part D Sponsor* submit the material on behalf of all the other *Plans/Part D Sponsors*, or have the piece submitted and approved by CMS prior to use for each *Plan/Part D Sponsor* mentioned. Materials that

indicate the provider has an affiliation with certain *Plans/Part D Sponsors* and that only list plan names and/or contact information do not require CMS approval.

70.11.3 - SNP Provider Affiliation Information

42 CFR 422.2268, 423.2268

Plans/Part D Sponsors may allow contracted providers to feature SNPs in a mailing announcing an ongoing affiliation. This mailing may highlight the provider's affiliation or arrangement by placing the SNP affiliations at the beginning of the announcement and may include specific information about the SNP *and must include the appropriate disclaimer (refer to section 50).* This includes providing information on special plan features, the population the SNP serves, or specific benefits for each SNP. The announcement must list all other SNPs with which the provider is affiliated.

70.11.4 - Comparative and Descriptive Plan Information

42 CFR 422.2268, 423.2268

Plans/Part D Sponsors may allow contracted providers to distribute printed information provided by a *Plan/Part D Sponsor* to their patients comparing the benefits of all of the different plans with which they contract. *Materials must include the appropriate disclaimer (refer to section 50.2).* Materials may not "rank order" or highlight specific plans and should include only objective information. Such materials must have the concurrence of all *Plans/Part D Sponsors* involved in the comparison and must be approved by CMS prior to distribution, (i.e., these items are not be subject to File & Use). The *Plan/Part D Sponsor* must determine a lead plan to coordinate submission of these materials (refer to § 90.2 for more information on submission of marketing materials).

70.11.5 - 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 Sponsor 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 § 40.11.3.

80 - Telephonic Activities and Scripts

80.1 - Customer Service Call Center Requirements

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

Plans/Part D Sponsors must operate a toll-free call center for both current and prospective enrollees seven (7) days a week, at least from 8:00 A.M. to 8:00 P.M., according to the time zones for the regions in which they operate. Current and prospective enrollees must be able to speak with a live customer service representative. *Plans/Part D Sponsors* may use alternative technologies on Thanksgiving and Christmas Day. For example, a *Plan/Part D Sponsor* may use an interactive voice response system or similar technologies to provide the required information listed below, and/or allow a beneficiary to leave a message in a voice mail box. A customer service representative must then return the call in a timely manner, no more than one business day later.

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

Call centers must meet the following operating standards:

- Provide information in response to inquiries outlined in § *80.3-80.5*.
- Follow an explicitly defined process for handling customer complaints.
- Provide interpreter service to all non-English speaking, limited English proficient and hearing impaired beneficiaries.
- Inform callers that interpreter services are "free."
- Limit average hold time to two (2) minutes. The average hold time is defined as the time spent on hold by the caller following the interactive voice response (IVR) system, touch tone response system, or recorded greeting and before reaching a live person.
- Answer eighty (80) percent of incoming calls within thirty (30) seconds.
- Limit the disconnect rate of all incoming calls to five (5) percent.

For Pharmacy Technical Help or Coverage Determinations and Appeals Call Center requirements refer to Appendix 4.

80.*2* – Requirements for Informational Scripts

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

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

> Example: A beneficiary calls customer service and requests to hear information about a particular plan. Based on the information provided, the beneficiary states that s/he wants to enroll in the plan. The customer service representative may process the enrollment and/or transfer the call to the appropriate area for processing because the beneficiary initiated the request.

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

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

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

- Formulary information
- Pharmacy information, including whether a beneficiary's pharmacy is in the *Plan's/Part D Sponsor's* network
- Provider information, including whether a beneficiary's physician is in the *Plan's/Part D Sponsor'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
- Information on how to obtain needed forms
- Information on replacing a member identification card
- Service area information

Plan sponsors *Plans/Plan Sponsors may* NOT:

- Include information about other lines of business in scripts.

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

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

- Use language in scripts that imply they are endorsed by Medicare, calling on behalf of Medicare, or that Medicare asked them to call the member.

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

80.3 - Requirements for Enrollment Scripts/Calls

42 CFR 422.60 (c), 423.32 (b)

Plans/Part D Sponsors are required to enter enrollment scripts into HPMS. CMS expects sponsors to incorporate in their scripts all relevant requirements outlined in these Medicare Marketing Guidelines (e.g., hours of operation, TTY number, etc.).

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

- Follow all guidance and requirements described in the CMS Eligibility and Enrollment Guidance in Chapters 2 and 17d of the Medicare Managed Care Manual and Chapter 2 of the Medicare Prescription Drug Benefit Manual.
- Clearly state the individual is requesting enrollment into [plan name] and the plan type.
- Provide confirmation of having accepted the telephone enrollment request, such as a confirmation tracking number or other tracking mechanism.
- Provide a statement that the individual will receive a notice acknowledging receipt of the enrollment,(e.g., acknowledging request for additional information or denial of enrollment).
- Provide contact information for questions including toll-free telephone and TTY numbers.

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

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

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

Any telephone sales scripts must be submitted *to HPMS* verbatim (bullets or talking points are unacceptable). *CMS expects sponsors to incorporate in their scripts all relevant requirements outlined in these Medicare Marketing Guidelines (e.g., hours of operation, TTY number, etc.).*

Plans must follow all telephone guidance in marketing through unsolicited contacts as noted in §§ 70.5 and 70.6. This guidance extends to all downstream contractors.

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

Sales calls must include a privacy statement clarifying that the beneficiary is not required to provide any health related information to the plan representative unless it will be used to determine enrollment eligibility.

90 - The Marketing Review Process

90.1 - *Part D Sponsor* Responsibilities

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

Plans/Part D Sponsors are responsible for conducting a quality check and ensuring that all materials are consistent with this chapter and all other relevant CMS issued guidance and instructions prior to submitting materials for review to CMS. Generally, CMS does not review marketing materials for typographical or grammatical errors, unless such errors render the marketing materials inaccurate or misleading.

90.2 - Material Submission Process

42 CFR 422.2262, 423.2262

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

If there are any changes or corrections to materials, (e.g., the benefit or cost-sharing information differs from that in the approved bid), the *Plan/Part D Sponsor* will be required to correct those materials for prospective

enrollees and send errata sheets/addenda/reprints to current members within a reasonable timeframe. If CMS finds that the sponsor failed to comply with applicable rules and guidance, we may take compliance action, including intermediate sanctions and civil money penalties.

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

90.2.1 - Submission of Non-English Materials or Alternative Formats

42 CFR 422.2264 (e), 423.2264(e)

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

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

90.2.2 - Submission of Websites for Review

42 CFR 422.2262, *422.2264,* 423.2262*, 423.2264*

Plans/Part D Sponsors must submit all MA, 1876 cost plan, and PDP websites for review. *Plans/Part D Sponsors* should submit their websites via links in a Word document. CMS expects reviewers to have an opportunity to review the link(s) provided as the information will be displayed in the marketplace. Therefore, the reviewer should be able to conduct the review online using the links provided in the Word document. Submitting screen shots or text in a word document is not acceptable. If the option to view online is not feasible, the organization should contact the Account Manager (prior to submission) and receive permission to submit information other than through a live link.

Once a *Plan's/Part D Sponsor's* website is reviewed and approved in entirety, a *Plan's/Part D Sponsor* may update specific pages of this same website by submitting only the pages to be changed via links on a Word document. Any updates to pages should be submitted with their own unique material ID and date stamped accordingly.

Plans/Part D Sponsors may make the website available for public use during the CMS review period; however, *Plans/Part D Sponsors* must include the status *pending* on their website until CMS has granted final

approval/disapproval. Use of the website while under CMS review applies only to the website text and not documents contained on the website, (e.g., a plan may not post an unapproved member handbook on the website).

If any portion of a *Plan's/Part D Sponsor's* website is disapproved, the *Plan/Part D Sponsor* must remove the disapproved portion immediately.

See § 100 for required website content.

90.2.*3* – Submission of Multi-Plan Materials

42 CFR 422.2262, 423.2262

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

Relevant terms for this process include:

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

The Coordinating Entity (CE) develops marketing materials in accordance with CMS requirements and coordinates with the Lead Plan (LP) to obtain CMS' approval on multi-plan marketing materials (the CMS Lead Region will be the region that has account management oversight and marketing review of the LP). The LP will inform the CE of approval who then communicates to

all Non-Lead Plans (NLPs) the material ID and original submission code so they may upload the multi-plan material in HPMS. Communications should occur via email for tracking and documentation purposes.

The LP must insert the following in the comments field:

- "MULTIPLAN MARKETING MATERIAL PRIMARY". This standardized text must be inserted in the first line of the comments field.
- The name and role of the CE who created the material (e.g., ABC FMO or XYZ PBM) must be inserted in the second line of the comments field.
- A list of all MCE or contract numbers for which the material is applicable.
- Any applicable information related to the piece that will assist CMS with the review.

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

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

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

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

- "MULTIPLAN MARKETING MATERIAL AUXILLARY". This standardized text must be inserted in the first line of the comments field.

- The name and role of the CE who created the material.
- A brief description of the material's previous submission history, including the "Primary" material ID (e.g., This Multiplan website was previously approved by CMS on Month/Day/Year. It was initially submitted by ABC123 Health Care under material ID [x].).

The material ID should be identical to the previously approved/accepted "Primary" material, with the exception of the *Plan's/Part D Sponsor's* (NLP) contract number.
NLP multi-plan marketing materials submitted for CMS review may not be used in the market place until approval from a plans' CMS reviewer is received. Materials submitted File & Use may not be distributed until the five calendar waiting period has passed.

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

90.3 - Material Dispositions

42 CFR 422.2262, 423.2262

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

90.3.1 - Approved Disposition

42 CFR 422.2262, 423.2262

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

> NOTE: Prior to having an executed contract with CMS, *Plans/Part D Sponsors*' marketing material dispositions will be considered "conditionally" approved.

90.3.2 - Disapproved Disposition

42 CFR 422.2262, 423.2262

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

90.3.3 - Deemed Disposition

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

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

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

The status of "Deemed" means that a *Plan/Part D Sponsor* may use the material.

90.3.4 - Withdrawn Disposition

42 CFR 422.2262, 423.2262

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

90.4 - Resubmitting Previously Disapproved Pieces

42 CFR 422.2262, 423.2262

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

90.5 - Time Frames for Marketing Review

42 CFR 422.2262(a) 423.2262(a)

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

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

90.6 - File & Use Program

42 CFR 422.2262(b), 423.2262(b)

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

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

Following are the certification procedures for Part D sponsors:

- Unless *a Part D Sponsor* requests a waiver from the File & Use Certification process, all *Part D Sponsors* must use the File & Use program.
- A *Part D Sponsor* may submit File & Use materials prior to executing a contract with CMS. By executing the CMS contract, the appropriate officer of the *Part D Sponsor* is attesting to his/her *plan's* compliance with the File & Use Certification requirements.

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

42 CFR 422.2262(b), 423.2262(b)

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

90.6.2 - Loss of File & Use Certification Privileges

42 CFR 422.2262(b), 423.2262(b)

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

- Uses materials that do not meet the requirements of this chapter;
- Fails to file material(s) at least five (5) calendar days prior to distribution or publication; or
- Is found to consistently submit a large number of File & Use materials through a forty-five (45) day review process, or to consistently submit through the File & Use process materials that do not meet the requirements of the MMG.

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

90.6.3 - File & Use Retrospective Monitoring Reviews

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

CMS will periodically conduct retrospective reviews of materials that were submitted under File & Use to ensure compliance by those plans that utilize this feature.

90.7 - Model Materials

42 CFR 422.2262 (c), 423.2262 (c)

CMS has developed certain model materials that are optional for use by *Plans/Part D Sponsors*; these are considered non-standardized model materials. *Plans/Part D Sponsors* that choose to modify the model language must ensure that all elements provided in the model are included in the non-model document. Model documents modified by the *Plan/Part D Sponsor* are subject to a forty-five (45) day review period. *Plans/Part D Sponsors are required to include the disclaimers from Section 50 in their modified model documents.* Generally, model documents used without modification will result in a ten (10) day marketing review period or may be submitted via File & Use.

"Without modification" means the *Plan/Part D Sponsor* used CMS model language verbatim except where indicated and allowed by CMS, (e.g., variable fields). To facilitate review, *Plans/Part D Sponsors* must indicate the model/exhibit title and applicable CMS chapter/manual or HPMS memorandum date within the comments section of HPMS.

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

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

Unless otherwise required, plans may choose to retain the title of the model document or modify the title to make it more beneficiary friendly. Any reference to the words "exhibit," "model," or "appendix" contained within the title of the model document must be removed. Any other modifications

made to the document will make the material subject to the standard forty-five (45) day review process and/or ineligible for File & Use submission.

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

90.7.1 - Standardized Language

42 CFR 422.2262 (c), 423.2262 (c)

Standardized language refers to language developed by CMS which is mandatory for use by *Plans/Part D Sponsors* and cannot be modified in any way.

90.7.2 - Required Use of Standardized Model Materials

42 CFR 422.2262 (c), 423.2262 (c)

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

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

90.8 - Template Materials

42 CFR 422.2262, 423.2262

A "template material" is any marketing material that includes placeholders for variable data to be populated at a later time by the *Plan/Part D Sponsor*. CMS classifies template materials as either standard templates or static templates. *Plans/Part D Sponsors* must submit the final populated version of standard templates in HPMS. Static templates include placeholders that are exempt from being submitted once populated.

Plans/Part D Sponsors should submit template materials using one "master document." *Plans/Part D Sponsors* must show how the placeholders in template materials will be populated by inserting the name of the field or listing all variables (e.g., "<date>", "<$10.00 Copay/$15.00 Copay>").

Populated standard templates must be submitted within thirty (30) days of use. *Plans/Part D Sponsors* are responsible for submitting final, populated versions of templates (except static templates) in the HPMS Marketing Module using the associated "Final Expedited Review" code, and will be required to enter the "Template Material ID" of the original "MASTER" template material in the "Template Material ID" field.

Changes to previously approved non-variable text in the template must be submitted for review and approval by CMS. If there are any changes or corrections to final materials, (e.g., the benefit or cost-sharing information differs from that in the approved bid), the *Plan/Part D Sponsor* will be required to correct those materials for prospective enrollees and send errata sheets/addenda/reprints to current members by a reasonable timeframe. In cases where non-compliance is discovered, the *Plan/Part D Sponsor* may be subject to penalties including intermediate sanctions and civil money penalties.

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

90.8.1 - Standard Templates

42 CFR 422.2262, 423.2262

A standard template is a marketing material that includes placeholders for variable data to be populated and resubmitted in HPMS at a later time. *Plans/Part D Sponsors* must submit the final material that has been populated (in the placeholders) with plan specific information. *Plans/Part D Sponsors* are required to indicate the "master" document is a template when submitting the material in HPMS.

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

90.8.2 - Static Templates

42 CFR 422.2262, 423.2262

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

The following variable data fields are exempt from the template resubmission requirement:

- Dates;
- Events;
- Addresses, phone or fax numbers;
- Hours of operation;
- Organization or company names;
- Plan name;
- Logos;
- Agent/Agency;
- Persons' names and pronoun variations;
- URLs;
- Member specific variables, (i.e., case numbers, drug specific references and *organization/*coverage determination decisions); and
- Co-branding information
- Photos
- Email addresses and web addresses
- LIS Rider
- OEV Scripts and Letters

90.8.3 - Template Materials Quality Review and Reporting of Errors

42 CFR 422.2262, 422.2264, 423.2262, 423.2264

CMS may conduct retrospective reviews, quality checks, or audits of populated templates. When errors are discovered, a *Plan/Part D Sponsor* must report the errors to its Account Manager. In addition, *Plans/Part D Sponsors* may be required to remedy the error by providing beneficiaries with updated information via errata sheets or addenda.

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

90.9 - Review of Materials in the Marketplace

42 CFR 422.2268, 423.2268

CMS periodically conducts reviews of *Plan/Part D Sponsor* materials. Reviews could include, but are not limited to, the following activities:

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

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

42 CFR 422.111(h), 423.128(d)

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

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

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

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

If a Plan/Part D Sponsor posts plan information to a social media site, it should also be verifiable through the Plan/Part D Sponsor's official website. For example, members of the public should be able to learn about the plan without having to join a third-party social media website.

All Plans/Part D Sponsors' social media pages should also provide a link back to the plan's official website.

100.1 - General Website Requirements

All *Plan/Part D Sponsor* websites must:

- *Follow all guidance within the MMG.*
- Maintain a separate and distinct section of their website for Medicare information if the *Plan/Part D Sponsor* markets other lines of business.
- Include the plan's toll-free customer service number and hours of operation, TTY number, and either a physical address or Post Office Box.
- Include the status *pending* until CMS has granted an approval/disapproval (Refer to 90.2.2).
- If there is a link on the sponsor's website that will take an individual to non-Medicare information the individual must be notified that by clicking on the link s/he will be leaving the Medicare information.
- Include a date/stamp on the bottom of each Web page with the date the page was last updated.
- Clearly label any links. When there is a link to a previously approved marketing material (e.g., SB, formulary, pharmacy/provider directory,) the plan must post the actual material, rather than duplicating the

material's content on the website. These materials must also retain their original Material ID.

- *For sponsors with service areas that meet the 5% language threshold, post* all required translated materials *in sections §§ 30.8, 30.9, and 30.12.*

100.2 - Required Content

All *Plan/Part D Sponsor* website content must be *updated monthly, as necessary,* and include:

- Information on beneficiaries' and plan's rights and responsibilities upon disenrollment.
- Service area listing.
- A list of premiums and cost-sharing (e.g., co-payments, co-insurance and deductibles) including any conditions and limitations.
- A list of any Out-of-Network Coverage rules.
- Instructions on how to appoint a representative and link to the CMS Appointment of Representative Form (CMS Form-1696).
- A description of and information on how to file a grievance, a *organization/*coverage determination and/or organization determination, and an appeal. This information must include:
    - Procedure for filing an *organization/*coverage determination.
    - Procedures for filing an organization determination.
    - Phone number(s) for receiving oral requests.
    - Mailing address for written requests.
    - Fax number for written requests.
    - Links, if applicable to any forms created by the plan for appeals and grievances.
    - Information on how to obtain an aggregate number of grievances, appeals, and exceptions filed with the *Plan/Part D Sponsor*.

    - Contact numbers that enrollees and/or physicians can use for process or status questions.
- A direct link to the Medicare.gov website where a beneficiary can enter a complaint in lieu of calling 1-800-Medicare.

- *The materials in Section 100.2.1.*

Part D sponsor website content must include:

- A direct link to CMS' Best Available Evidence policy on the CMS website.

- Direct links to the Request for Medicare Prescription Drug Determination Request Form(s) for enrollees and Providers found on CMS' Part D appeals webpage.

- Quality assurance policies and procedures, including Medication Therapy Management (MTM) information, and drug and/or utilization management information.

- Information about MTM programs including:

    - *Plans/Part D Sponsors*' eligibility criteria and conditions for which MTM programs are available,

    - High level summary of services offered as part of the MTM program,

    - A statement clarifying that these programs are not considered a benefit,

    - A statement informing beneficiaries to contact the *Plan's/Part D Sponsor's* customer service for additional information.

- *The materials in Section 100.2.2.*

PFFS Plan websites must include:

- A link to *Plan's/Part D Sponsor's* Terms and Conditions of Payment

MSA Plan websites must include the following statements:

- "You must file Form 1040, US Individual Income Tax Return, along with Form 8853, "Archer MSA and Long-Term Care Insurance Contracts" with the Internal Revenue Service (IRS) for any distributions made from your Medicare MSA account to ensure you

aren't taxed on your MSA account withdrawals. You must file these tax forms for any year in which an MSA account withdrawal is made, even if you have no taxable income or other reason for filing a Form 1040. MSA account withdrawals for qualified medical expenses are tax free, while account withdrawals for non-medical expenses are subject to both income tax and a fifty (50) percent tax penalty."

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

100.2.1 – Required Documents for All *Plans/Part D Sponsors*

All *Plans/Part D Sponsors* must post the following materials:

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

100.2.2 – Required Documents for Part D Sponsors

Part D *Plans/Part D Sponsors* must post the following materials *online*:

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

- LIS Premium Summary Chart

- *Pharmacy Directory*
- Prescription Drug Transition Policy

100.3 - Online Enrollment

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

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

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

Third party entities (on behalf of the *Plan/Part D Sponsor*) may make on-line enrollment available to potential enrollees via the *Plan's/Part D Sponsor's* website or the OEC ONLY.

Enrollment via an agent/broker website is not permitted.

100.4 – Online Provider Directory Requirements

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

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

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

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

The requirements in this section apply to online versions of formularies, UM documents, and notice.

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

The information in the website formulary must meet all of the requirements listed below. Utilization management documents must at a minimum fulfill the requirements listed in the first four bullets as well as any other applicable requirements listed below.

- Be available at the start of each new contract year enrollment period.
- Be updated at least once per month.
- *Be available through a link to a downloadable document. In addition, Part D sponsors may provide an on-line formulary search tool but such tools cannot be used as a substitute for the required downloadable documents.*
- Indicate when the document *and* search tool *(if available)* was last updated by including the phrase, "Updated MM/YYYY" or "No changes made since MM/YYYY*"; explain that members can contact the plan for the most recent list of drugs; and provide plan phone number, hours, and web address.*
- Define a *comprehensive* formulary (either in a link or through an introductory screen).
- Provide an explanation of how to use the search tool*, if available.*
- *Be accessible by a drug name search.*
- *The document must explain or link to an explanation of how to obtain an exception to the Part D plan's formulary, utilization management tools, or tiered cost sharing. This must be provided when search results indicate a drug is not covered.*
- *Part D Sponsors may include formulary and non-formulary alternatives; however, the formulary alternatives must be clearly*

marked as formulary drugs without the need for further navigation. If not all formulary alternatives will be listed, the plan must include the following disclaimer: "This is not a complete list of all formulary alternatives covered by the Part D plan for the drug you have selected".

- *Each search result that appears in the downloadable format or search tool must meet all the requirements bulleted below.*

- *Indicate whether a drug is covered, its tier placement, and any applicable utilization management requirements. If quantity limit restrictions apply, the quantity limit amount and days' supply must be displayed. If prior authorization or step therapy restrictions are applicable, then the criteria must also be included.*
- For drugs with a Part B versus D administrative prior authorization requirement, the following statement must be included: "This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination".

- *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 plan's formulary, utilization management tools or tiered cost sharing. This information or a link to this information must be included in both an introductory screen and when search results indicate a drug is not covered.

- *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).

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

The online formulary change notice must *meet all requirements for written notice specified in the Prescription Drug Manual, Chapter 6, § 30.3.4 (http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/downloads/Chapter6.pdf), which includes name of drug, nature of the change (removed or changed drug to preferred or cost-sharing status); reason for the change; list of alternative*

drugs and expected cost-sharing; and information on obtaining coverage determination or exception thereto.

110 - Reserved

120 - Marketing and Sales Oversight and Responsibilities

120.1 - Compliance with State Licensure and Appointment Laws

42 CFR 422.2272(c), 423.2272 (c)

In order to sell Medicare products, *Plans/Part D Sponsors* must comply with applicable State licensure and/or appointment laws.

120.2 - Plan Reporting of Terminated Agents

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

Plans/Part D Sponsors must report the termination of any brokers or agents and the reasons for the termination to the State in which the broker or agent has been appointed in accordance with the State appointment law.

When *Plans/Part D Sponsors* discover incidents of unlicensed agents or brokers submitting applications, they must terminate the agent/broker and report them to the authority in the State where the application was submitted. Additionally, *Plans/Part D Sponsors* must notify any beneficiaries that were enrolled in their plans by unqualified agents or brokers and advise those beneficiaries of the agents' and brokers' status. Beneficiaries may request to make a plan change.

120.3 - Agent/Broker Training and Testing

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

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

Specifications for training/testing criteria and documentation requirements will be provided annually by CMS. *Plans/Part D Sponsors* must ensure that their training and testing programs are designed and implemented in a way

that maintains the integrity of the training and testing, and must have the ability to provide this information to CMS upon request.

120.4 - Agent/Broker Compensation

42 CFR 422.2274(a), 423.2274(a)

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

120.4.1 - Definition of Compensation

42 CFR 422.2274, 423.2274

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 finder's fees.

Compensation DOES NOT include:

- The payment of fees to comply with State appointment laws
- Training
- Certification
- Testing costs
- Reimbursement for mileage to, and from, appointments with beneficiaries
- Reimbursement for actual costs associated with beneficiary sales appointments such as venue rent, snacks, and materials

120.4.2 - Compensation Types

42 CFR 422.2274(a), 423.2274(a)

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

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

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

A "like plan type" enrollment includes:

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

An "unlike plan type" enrollment includes:

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

  NOTE: For dual enrollments, (e.g., enrollment in an MA-only plan and a stand-alone PDP), the compensation rules apply independently to each plan. However, when dual enrollments are replaced by an enrollment in a single plan, compensation is paid based on the MA movement, (e.g., movement from an MA-only plan and PDP to an MA-PD plan would be compensated at the renewal compensation amount for the MA to MA-PD "like plan type" move).

120.4.3 - Compensation Cycle (6-Year Cycle)

42 CFR 422.2274(a), 423.2274(a)

Plans/Part D Sponsors are required to pay independent agents/brokers on a 6-year compensation cycle. The first year is the initial year followed by 5 renewal years. If during a 6-year cycle, a plan member moves to a plan of a

different plan type, the agent or broker may receive an initial compensation and the six (6)-year cycle starts over again. Once the compensation cycle expires, it does not restart until the beneficiary enrolls into another plan. *Plans/Part D Sponsors* may continue to pay agents or brokers renewal compensation beyond the six (6)-year cycle at the plan's discretion, as described in § 120.4.5. The monthly MARx agent/broker compensation report that is generated when an enrollment occurs will provide *Plans/Part D Sponsors* with the information necessary to determine whether they should make an initial or renewal payment.

120.4.4 - Developing and Implementing a Compensation Strategy

42 CFR 422.2274(a), 423.2274(a)

Following is specific guidance for *Plans/Part D Sponsors* as they develop or modify their agent/broker compensation strategy.

- CMS defines "year" as a plan year, meaning January 1 through December 31. *Regardless of when a beneficiary enrolls into a plan during the year, for purposes of the 6-year compensation cycle, the year ends on December 31st.*

- For example, if a beneficiary's enrollment is effective on September 1, then the initial year for that beneficiary ends on December 31, even though the beneficiary has only been in the plan for four (4) months. In January of the next year, the plan would begin paying renewal payments to the agent that assisted this beneficiary.

- When a beneficiary enrolls after January 1, the *Plan/Part D Sponsor* must pay the agent/broker at the initial compensation level during that calendar year but may pay either the full commission or a pro-rated amount based upon the number of months the beneficiary was enrolled.

- For the purpose of calculating compensation, the movement by a beneficiary from an employer group plan to an individual plan (either within the same *Part D Sponsor* or between different *Plan/Part D Sponsors*) counts as an initial enrollment.

- *Plans/Part D Sponsors* must not pay agents who are no longer appointed to sell in the State (if required), have not been annually trained and tested per the plan's policies and procedures with a passing score of at least eighty-five (85) percent, or have been terminated for cause by the plan.
- CMS compensation requirements do not apply to employed agents.

- If a contracted agent represents a single *Plan/Part D Sponsor* and is paid a fixed amount of money that does not vary based on enrollment, that agent may be considered employed for purposes of applying CMS agent/broker compensation requirements.
- *Plans/Part D Sponsors* cannot pay agent/brokers for the entire 6-year compensation cycle upfront, but may pay them annually, quarterly, monthly, or more frequently.
- *For Medicare beneficiaries enrolling in a plan mid-year and having no prior plan history as indicated on the compensation report Plans/Part D Sponsors may pay the full year initial compensation amount.*
- Referral/finder's fees are part of total compensation. They are not subject to the six (6)-year compensation cycle.
- Bonuses (announced or unannounced prior to payment) must be included in compensation schedules and fall within CMS rules. A bonus does not fall outside CMS rules because it was not announced to agents or brokers in advance.
- Compensation for dual enrollments should be paid independently, (e.g., when a beneficiary enrolls in both a section 1876 cost plan and a stand-alone PDP, compensation should be paid for both enrollments).
- When a beneficiary enrolls in an MA-PD plan, compensation should be paid using the MA compensation amount. *Plans/Part D Sponsors* should not pay both the MA and PDP compensation amounts.
- A *Plan/Part D Sponsor* will have the opportunity prior to each contract year to determine that it will no longer use independent agents and brokers. When a *Plan/Part D Sponsor* and/or a contracted independent agent or broker elect to terminate their contract, any remaining cycle years of existing business will be governed by the terms of that contract.

120.4.5 - Compensation Calculation

42 CFR 422.2274(a), 423.2274(a)

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

120.4.6 - Recovering Compensation Payments (Charge-backs)

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

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

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

Plans/Part D Sponsors should pay only for the actual months the beneficiary is enrolled in the plan. *Plans/Part D Sponsors* should not recover funds when a beneficiary disenrolls within the first three months under the circumstances described below:

- Disenrollment from Part D due to:
- Other creditable coverage
- Institutionalization
- Under the following exceptional circumstances:
    - Gains/drops employer/union sponsored coverage
    - Because of a CMS sanction against the plan
    - Because of plan terminations
    - Because of a non-renewing section 1876 cost plan
    - During the Medigap trial period
    - In order to coordinate with Part D enrollment periods
    - In order to coordinate with an SPAP
- Due to following changes in status:

        - Becoming dually eligible for both Medicare and Medicaid
        - Qualifying for another plan based on special needs
        - Becoming LIS eligible
        - Qualifying for another plan based on a chronic condition
        - Moves into or out of institution
    - Due to an auto- or facilitated enrollment
    - Involuntarily disenrollment for one of the following reasons:
        - Death
        - Moves out of the service area
        - Non-payment of premium
        - Loss of entitlement
        - Retroactive notice of Medicare entitlement
        - Contract violation
        - Plan non-renewal or termination
- When moving to a plan with a 5-Star rating *or out of a low performing plan.*

120.4.7 - Adjustments to Compensation Schedules

42 CFR *422.2274(a)(5)and (6); 422.2274(f); 423.2274(a)(5)and (6); 423.2274(f)*

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

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

120.5 - Third Party Marketing Entities

42 CFR 422.2274(a), 423.2274(a)

If the *Plan/Part D Sponsor* contracts with a third party entity such as a TMO or a similar type of entity to sell its insurance products or perform services, (e.g., training, customer service, or agent recruitment), the amount paid to the third-party for the enrollment must be consistent with the compensation requirements (See § 120.4). The amount paid to the third-party for other services must be of FMV and must not exceed an amount that is commensurate with the amounts paid by the *Plan/Part D Sponsor* to a third party for similar services during each of the previous two (2) years.

120.6 - Additional Marketing Fees

42 CFR 422.2274(a), 423.2274(a)

A *Plan/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*.

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

42 CFR 422.*2272*(c), 423.*2272*(c)

CMS clarifies that the following activities *conducted by a plan customer service representative* do not require the use of a State-licensed marketing representative. These include the following:

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

130 - Employer/Union Group Health Plans

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

As provided in § 10.1 of Chapter 9 of the Medicare Managed Care Manual and § 10.1 of Chapter 12 of the Prescription Drug Benefit Manual, CMS has authority under sections 1857(i) and 1860D-22(b) of the Social Security Act to waive or modify requirements that hinder the design of, the offering of, or the enrollment in employment-based Medicare plans offered by employers and unions to their members. Waivers and modifications may be granted to *Plans/Part D Sponsors* offering "individual" PDPs or MA plans, or *Plans/Part D*

Sponsors offering customized employer group PDPs or MA plans offered exclusively to employer/union group health *Plans/Part D Sponsors* (known as employer/union-only group waiver plans, or EGWPs). CMS has issued various employer group waivers and/or modifications to the Medicare Part C and Part D rules for marketing and disclosure/dissemination of information to Medicare beneficiaries. For specific guidance regarding these waivers or modifications of marketing and disclosure/dissemination of information requirements for employer/union-sponsored group health plans, please refer to Chapter 9 of the Medicare Managed Care Manual, and Chapter 12 of the Prescription Drug Benefit Manual.

Plans/Part D Sponsors offering employer group health plans are no longer required to submit informational copies of their dissemination materials to CMS at the time of use. However, as a condition of CMS providing these particular waivers or modifications, CMS reserves the right to request and review these materials in the event of beneficiary complaints or for any other reason it determines to ensure the information accurately and adequately informs Medicare beneficiaries about their rights and obligations under the plan. For more information about these requirements, refer to 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.

Provision	Yes	No
Nominal Gifts	X	
Unsolicited Contacts		X
Cross-selling		X
Scope of Appointments		X
Sales/Marketing in Health Care Settings	X	
Sales/Marketing at Educational Events	X	
Co-branding	X	
Provision of Meals		X
Appointment of Agents/Brokers	X	

State Licensed	X	
Reporting of Terminated Agents/Brokers	X	
Agent/Broker Compensation		X
Agent/Broker Training and Testing – Agents must be thoroughly familiar with the products they are selling; including the plan specific details and the Medicare rules that apply to the specific products. The organization/sponsor is responsible for ensuring that the agents selling for them have sufficient knowledge.	X (training)	X (testing)

140 - Medicare Medical Savings Account (MSA) Plans

42 CFR 422.2264, 423.2264

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

Additionally, MSA plans may not:

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

See § 100 for additional MSA requirements related to websites.

150 - Use of Medicare Mark For Part D Plans

Section 1140 of the Social Security Act

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

150.1 - Authorized Users for Medicare Mark

Section 1140 of the Social Security Act

All Part D plans are authorized to use the Medicare Prescription Drug Benefit Program Mark only after *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 plans may use the mark on marketing materials consistent with this chapter.

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

Section 1140 of the Social Security Act

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

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

Section 1140 of the Social Security Act

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

1. *The Part D Sponsor electronically signs the Medicare Mark License Agreement in HPMS (or signs a hardcopy, as applicable).*

2. CMS counter-signs the *Part D Sponsor's* contract.

3. CMS sends the Medicare Mark URL to the *Part D Sponsor*.

After receipt of the URL, organizations may begin using the mark on marketing materials (including the Part D membership ID card) that are required to be submitted to CMS for review.

Requests to distribute other items (materials that are not included in this chapter) bearing the Medicare Prescription Drug Benefit Program Mark must be submitted to CMS at least thirty (30) days prior to the anticipated date of distribution. Requests should be sent to: CMS External Affairs Office/Visual & Multimedia Communications Group at 7500 Security Blvd., Baltimore, MD 21244-1850, Mail Stop: C1-16-03.

Once a request has been approved the following will apply: 1) approval will be effective for a period not to exceed one year; and 2) approval will be

granted only for those items for which use of the mark was requested in the request letter and for which written approval was granted.

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

Section 1140 of the Social Security Act

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

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

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

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

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

150.6 - Mark Guidelines

Section 1140 of the Social Security Act

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

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

150.6.1 - Mark Guidelines - Negative Program Mark

Section 1140 of the Social Security Act

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

150.6.2 - Mark Guidelines - Approved Colors

Section 1140 of the Social Security Act

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

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

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

150.6.3 - Mark Guidelines on Languages

Section 1140 of the Social Security Act

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

150.6.4 - Mark Guidelines on Size

Section 1140 of the Social Security Act

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

150.6.5 - Mark Guidelines on Clear Space Allocation

Section 1140 of the Social Security Act

The clear space around the Medicare Prescription Drug Benefit Program Mark prevents any nearby text, image or illustration from interfering with the legibility and impact of the mark. The measurement “x” can be defined as

the height of the letter “x” in “Rx” in the Program Mark. Any type or graphic elements must be at least “x” distance from the mark as shown by the illustration.

150.6.6 - Mark Guidelines on Bleed Edge Indicator

Section 1140 of the Social Security Act

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

150.6.7 - Mark Guidelines on Incorrect Use

Section 1140 of the Social Security Act

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

- Do not alter the position of the mark elements.
- Do not alter the aspect ratio of the certification mark. Do not stretch or distort the mark.
- Always use the mark as provided.
- Do not rotate the mark or any of its elements.
- Do not alter or change the typeface of the mark.
- Do not alter the color of any of the mark elements.
- Do not position the mark near other items or images. Maintain the clear space allocation.
- Do not position the mark to bleed off any edge. Maintain one-eight (1/8) inch safety from any edge.
- Do not use any of the mark elements to create a new mark or graphic.

- Do not use the mark on background colors, images or other artwork that interfere with the legibility of the mark.

150.7 - Part D Standard Pharmacy ID Card Design

Section 1140 of the Social Security Act

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

160 - Allowable Use of Medicare Beneficiary Information Obtained from CMS

All MA, Part D, PACE, and section 1876 cost plans sign a data use attestation under which they agree that they will restrict the use of Medicare data to those purposes directly related to the administration of the Medicare managed care and/or outpatient prescription drug benefits for which they have contracted with CMS to administer. *Plans/Part D Sponsors* also agree not to use that information to develop, market, or operate lines of business unrelated to their Medicare plan operations.

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

sponsor was only given the information on the application as a result of the contract with CMS.

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

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

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

160.1 - When Prior Authorization From the Beneficiary Is Not Required

Plan/Part D Sponsor marketing materials describing health-related lines of business to current members do not require prior authorization (See 40.11 for additional information). Examples of health-related information that do not require prior authorization include:

- Long-term care insurance
- Separate dental or vision policies
- Health-related value-added items and services (VAIS)
- Information about current plan coverage or other Medicare products offered by the *Plan/Part D Sponsor*
- Plan and health information in monthly newsletters

- Information on disease management programs
- Mailings describing benefits changes
- Information on Medicaid and other community or social services program

160.2 - When Prior Authorization From the Beneficiary Is Required

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

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

160.3 - Obtaining Prior Authorization

Following are examples of how the prior authorization required under §160.2 may be obtained. With any of these examples, *Plans/Part D Sponsors* must receive the member's "opt-in" authorization prior to sending any non-plan or non-health related information, and *Plans/Part D Sponsors* should keep evidence of authorization for audit purposes.

- *Plans/Part D Sponsors* may send, at their own expense, written requests to enrollees to obtain the beneficiary's authorization for the organization or sponsor to contact him/her for purposes unrelated to plan benefits administration or CMS contract execution. The beneficiary must sign and return the request before the plan can send non-plan related materials or information. This authorization may also be obtained by directing a beneficiary to a website to provide the requisite consent. Note that if the plan uses a website for the "opt-in" process, the link from the plan's Medicare product website must inform

the beneficiary that he or she is leaving the Medicare product website and going to the non-Medicare product website, as provided in § 100.1. Once a beneficiary "opts-in," the *Plans/Part D Sponsors* must be clear that the beneficiary will receive additional information that may be non-plan or non-health related.

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

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

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

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

- The request must include one or more types of information for which authorization is being sought. If authorization is being sought for more than one type of information, a check box (or verbal agreement, if a telephonic authorization) needs to be assigned to each type of information. Furthermore, the type of information can only be described in general terms. For example, "Check the boxes of the types of information you would like to receive: life insurance, long-term care insurance, pending State and Federal legislation, grass-roots advocacy."

- The request for authorization should not include any non-plan or non-health related content, nor should it be included in the same mailing as information on non-health related issues, unless the *Plan/Part D Sponsor* has previously received prior authorization to send that particular non-health related information to that member. For example, a request for authorization to send information about life insurance should not include a statement like "Make sure your spouse's future is secure, with a life insurance policy from us," and/or should not be sent with documents that include details about the life insurance policy.

- The request for authorization can be included in the same mailing as plan-related or health-related mailings to members, as provided in the MMG. The request for authorization may not be included on the enrollment form (whether in hard copy or in electronic forms available

via the plan's website) or made during the processing of a telephonic enrollment.

- The request for authorization should not be confusing or misleading to members by purporting to have current plan benefit information or by suggesting that the content includes official information from the Medicare program.

- These requests for authorization are not subject to review by CMS, and should not be uploaded into HPMS. However, per § 20, *Plans/Part D Sponsors* are still responsible for ensuring that all materials intended for Medicare beneficiaries meet the requirements of this chapter.

- CMS is adopting the same requirements for these authorizations as required by the HIPAA Privacy Rule. Additional details on what is required for an acceptable attestation can be found at 45 CFR 164.508.

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

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

- Non-health related content cannot be delivered with plan-related materials; including in mailings, on websites, or during outbound telephone calls related to current plan information.

- Health-related content can be included with plan-related materials.

In addition, these materials should include the disclaimer, "Medicare has neither reviewed, nor endorses, this information".

Appendix 1 - Definitions

422.2260; 423.2260, 422.2268, 423.2268The 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 member-specific claims processing or other operational issues*, and which do not include information about the plan's benefit structure. These materials are not considered marketing materials *and may not mislead or confuse Medicare beneficiaries, or misrepresent the MA organization*. Examples of these materials include the following:

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

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

Advertising

Advertising materials are primarily intended to attract or appeal to a potential *Plan/Part D Sponsor* enrollee. Advertising materials contain less detail than other marketing materials, and may provide benefit information at a level to entice a potential enrollee to request additional information.

Alternate Formats

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

Banner and Banner-Like Advertisements

Banner advertisements are typically used in television ads, and flash information quickly across a screen with the sole purpose of enticing a

prospective enrollee to contact the *Plan/Part D Sponsor* to enroll or for more information. A "banner-like" advertisement is usually in some media other than television, (e.g., outdoor advertising and internet banner ads), and is intended to be very brief and to entice someone to call the *Plan/Part D Sponsor* or to alert someone that information is forthcoming.

Co-Branding

Co-branding is defined as a relationship between two or more separate legal entities, one of which is an organization that sponsors a Medicare plan. The Plan/Part D Sponsor displays the name(s) or brand(s) of the co-branding entity or entities on its marketing materials to signify a business arrangement. Co-branding arrangements allow a Plan/Part D Sponsor and its co-branding partner(s) to promote enrollment in the plan. Co-branding relationships are entered into independent of the contract that the Plan/Part D Sponsor has with CMS.

Direct mail

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

Educational Event

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

Enrollment Materials

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

Joint Enterprise

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

Marketing

Marketing is the act of steering, or attempting to steer, a potential enrollee towards a plan or limited number of plans, or promoting a plan or a number of plans.

Marketing Materials

Marketing materials are any materials targeted to Medicare beneficiaries that:

1. Promote the *Plan/Part D Sponsor*, or any MA plan, MA-PD plan, section 1876 cost plan, or PDP offered by the *Plan/Part D Sponsor*.

2. Inform Medicare beneficiaries that they may enroll, or remain enrolled in, an MA plan, MA-PD plan, section 1876 cost plan, or PDP offered by the *Plan/Part D Sponsor*.

3. Explain the benefits of enrollment in an MA plan, MA-PD plan, section 1876 cost plan, or PDP or rules that apply to enrollees.

4. Explain how Medicare services are covered under an MA plan, MA-PD plan, section 1876 cost plan or PDP plan, including conditions that apply to such coverage.

Marketing/Sales Event

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

Marketing Appointments

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

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

Generally speaking, CMS categorizes scripts as either informational in nature or related to sales/enrollment. Informational scripts are designed to respond to beneficiary questions and requests and provide objective

information about the plan and Medicare program. Sales and enrollment scripts are intended to steer a beneficiary towards a plan or limited number of plans and those used to enroll a beneficiary into a plan.

Standardized Language

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

Template Materials

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

Third Party Marketing Organization (TMO)

Third-party marketing organizations are entities such as a Field Marketing Organization (FMO), General Agent (GA), or similar type of organization that has been retained to sell or promote a *Plan's/Part D Sponsor's* Medicare products on the *Plan's/Part D Sponsor's* behalf either directly or through sales agents or a combination of both.

Value Added Items and Services (VAIS)

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

Appendix 2 – Related Laws and Regulations

(Not an exhaustive list)

Use of the Medicare Name

Section 1140 of the Social Security Act

Under Section 1140 of the Social Security Act, 42 U.S.C. 1320b–10, it is forbidden for any person to use words or symbols, including "Medicare," "Centers for Medicare & Medicaid Services," "Department of Health and Human Services," or "Health & Human Services" in a manner that would convey the false impression that the business or product mentioned is approved, endorsed, or authorized by Medicare or any other government agency. This rule extends to downstream contractors that may be directly or indirectly involved in marketing Medicare plans. *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, 422.752(a)(4), 423.136, 423.752(a)(4)

Plans/Part D Sponsors and providers are responsible for following all Federal and State laws regarding confidentiality and disclosure of patient information to *Plans/Part D Sponsors* for marketing purposes. This obligation includes compliance with the provisions of the HIPAA Privacy Rule and its specific rules regarding uses and disclosures of beneficiary information. HIPAA and privacy documents, (e.g., a HIPAA/privacy document for a beneficiary's signature in a provider's office), are not considered marketing documents and therefore do not need to be submitted in HPMS. Refer to § 20 regarding materials not subject to review. Additional information on the HIPAA Privacy Rule and its disclosure requirements can be found at http://www.hhs.gov/ocr/privacy/.

Multiple Lines of Business - HIPAA Privacy Rule

45 CFR 160

Generally, *Plans/Part D Sponsors* are not required to obtain authorization from enrollees to use or disclose an enrollee's protected health information with regard to providing communication about replacements of or enhancements to the *Plan's/Part D Sponsor's* benefits or the *Plan's/Part D Sponsor's* health-related value added products and services. These categories are exceptions to the definition of marketing in the HIPAA Privacy

Rule. In complying with these exceptions, *Plans/Part D Sponsors* may use and disclose protected health information to make communications to enrollees about other lines of business provided by the covered entity.

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

Telephonic Contact

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

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

Use of Federal Funds

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

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

Section 508 of the Rehabilitation Act

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

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

> NOTE: These Federal requirements are extended to all *Plans/Part D Sponsors* through the requirements for non-discrimination under Federal grants and programs (29 USC §794).

Mailing Standards

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

Appendix *3* – Multi-Language Insert

Multi-language Interpreter Services

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

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

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

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

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

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

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

German: Unser kostenloser Dolmetscherservice beantwortet Ihren Fragen zu unserem Gesundheits- und Arzneimittelplan. Unsere Dolmetscher

erreichen Sie unter [1-xxx-xxx-xxxx]. Man wird Ihnen dort auf Deutsch weiterhelfen. Dieser Service ist kostenlos.

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

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

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

Hindi[1]: हमारे स्वास्थ्य या दवा की योजना के बारे में आपके किसी भी प्रश्न के जवाब देने के लिए हमारे पास मुफ्त दुभाषिया सेवाएँ उपलब्ध हैं. एक दुभाषिया प्राप्त करने के लिए, बस हमें [1-XXX-XXX-XXXX] पर फोन करें. कोई व्यक्ति जो हिन्दी बोलता है आपकी मदद कर सकता है. यह एक मुफ्त सेवा है.

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

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

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

* Please note that Arabic and Hindi text appear in the MMG word version of the MMG only.

Polish: Umożliwiamy bezpłatne skorzystanie z usług tłumacza ustnego, który pomoże w uzyskaniu odpowiedzi na temat planu zdrowotnego lub dawkowania leków. Aby skorzystać z pomocy tłumacza znającego język polski, należy zadzwonić pod numer [1-xxx-xxx-xxxx]. Ta usługa jest bezpłatna.

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

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

Pharmacy Technical Help Call Center Requirements

42 CFR 423.128(d)(1)

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

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

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

Plan/Part D Sponsor Determinations and Appeals Call Center Requirements

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

All *Plan/Part D Sponsors* (except 1876 cost *Plan/Part D Sponsor*s that do not offer Part D) must operate a toll-free call center with live customer service representatives available to respond to providers or enrollees for information related to coverage determinations (including exceptions and prior authorizations), appeals. *Plans/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 and never less than from 8:00 a.m. to 6:00 p.m., Monday through Friday; according to the time zones for the regions in which they operate. *Plans/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 provided the message:

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