

(iv) CMS Star Ratings document, which must be posted within 21 days after its release on the Medicare Plan Finder.

[86 FR 6125, Jan. 19, 2021, as amended at 87 FR 27901, May 9, 2022]

§ 423.2266 Activities with healthcare providers or in the healthcare setting.

(a) *Where marketing is prohibited.* The requirements in paragraphs (c) through (e) of this section apply to activities in the health care setting. Marketing activities and materials are not permitted in areas where care is being administered, including but not limited to the following:

- (1) Exam rooms.
- (2) Hospital patient rooms.

(3) Treatment areas where patients interact with a provider and his/her clinical team and receive treatment (including such areas in dialysis treatment facilities).

- (4) Pharmacy counter areas.

(b) *Where marketing is permitted.* Marketing activities and materials are permitted in common areas within the health care setting, including the following:

- (1) Common entryways.
- (2) Vestibules.
- (3) Waiting rooms.
- (4) Hospital or nursing home cafeterias.

(5) Community, recreational, or conference rooms.

(c) *Provider-initiated activities.* Provider-initiated activities are activities conducted by a provider at the request of the patient, or as a matter of a course of treatment, and occur when meeting with the patient as part of the professional relationship between the provider and patient. Provider-initiated activities do not include activities conducted at the request of the Part D sponsor or pursuant to the network participation agreement between the Part D sponsor and the provider. Provider-initiated activities that meet this definition in this paragraph (c) fall outside of the definition of marketing in § 423.2260. Permissible provider-initiated activities include:

(1) Distributing unaltered, printed materials created by CMS, such as reports from Medicare Plan Finder, the

“Medicare & You” handbook, or “Medicare Options Compare” (from <https://www.medicare.gov>) including in areas where care is delivered.

(2) Providing the names of Part D sponsors with which they contract or participate or both.

(3) Answering questions or discussing the merits of a Part D plan or plans, including cost sharing and benefit information including in areas where care is delivered.

(4) Referring patients to other sources of information, such as State Health Insurance Assistance Program (SHIP) representatives, plan marketing representatives, State Medicaid Office, local Social Security Offices, CMS’ website at <https://www.medicare.gov>, or 1-800-MEDICARE.

(5) Referring patients to Part D marketing materials available in common areas.

(6) Providing information and assistance in applying for the LIS.

(7) Announcing new or continuing affiliations with Part D sponsors, once a contractual agreement is signed. Announcements may be made through any means of distribution.

(d) *Plan-initiated provider activities.* Plan-initiated provider activities are those activities conducted by a provider at the request of a Part D sponsor. During a plan-initiated provider activity, the provider is acting on behalf of the Part D sponsor. For the purpose of plan-initiated activities, the Part D sponsor is responsible for compliance with all applicable regulatory requirements.

(1) During plan-initiated provider activities, Part D sponsors must ensure that the provider does not:

(i) Accept/collect scope of appointment forms.

(ii) Accept Medicare enrollment applications.

(iii) Make phone calls or direct, urge, or attempt to persuade their patients to enroll in a specific plan based on financial or any other interests of the provider.

(iv) Mail marketing materials on behalf of a Part D sponsor.

(v) Offer inducements to persuade patients to enroll with a particular Part D plan or sponsor.

(vi) Conduct health screenings as a marketing activity.

(vii) Distribute marketing materials or enrollment forms in areas where care is being delivered.

(viii) Offer anything of value to induce enrollees to select the provider.

(ix) Accept compensation from the Part D sponsor for any marketing or enrollment activities performed on behalf of the Part D sponsor.

(2) During plan-initiated provider activities, the provider may do any of the following:

(i) Make available, distribute, and display communications materials, including in areas where care is being delivered.

(ii) Provide or make available marketing materials and enrollment forms in common areas.

(e) *Part D sponsor activities in the healthcare setting.* Part D sponsor activities in the health care setting are those activities, including marketing activities that are conducted by Part D sponsor or on behalf of the Part D sponsor, or by any downstream entity, but not by a provider. All marketing must comply with the requirements in paragraphs (a) and (b) of this section. However, during Part D sponsor activities, the following is permitted:

(1) Accepting and collect Scope of Appointment forms.

(2) Accepting enrollment forms.

(3) Making available, distributing, and displaying communications materials, including in areas where care is being delivered.

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§ 423.2267 Required materials and content.

For information CMS deems to be vital to the beneficiary, including information related to enrollment, benefits, health, and rights, the agency may develop materials or content that are either standardized or provided in a model form. Such materials and content are collectively referred to as required.

(a) *Standards for required materials and content.* All required materials and content, regardless of categorization as standardized in paragraph (b) of this section or model in paragraph (c) of this section, must meet the following:

(1) Be in a 12pt font, Times New Roman or equivalent.

(2) For markets with a significant non-English speaking population, be in the language of these individuals. Specifically, Part D sponsors must translate required materials into any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area.

(3) Be provided to enrollees on a standing basis in any non-English language identified in paragraphs (a)(2) and (4) of this section and/or accessible format using auxiliary aids and services upon receiving a request for the materials in a non-English language or accessible format or when otherwise learning of the enrollee's primary language and/or need for an accessible format. This requirement also applies to the individualized plans of care described in § 422.101(f)(1)(ii) of this chapter for special needs plan enrollees.

(4) For any fully integrated dual eligible special needs plan or highly integrated dual eligible special needs plan as defined at § 422.2 of this chapter, or applicable integrated plan as defined at § 422.561 of this chapter, be translated into the language(s) required by the Medicaid translation standard as specified through their capitated Medicaid managed care contract in addition to the language(s) required by the Medicare translation standard in paragraph (a)(2) of this section.

(5) Be provided to the beneficiary within CMS's specified timeframes.

(b) *Standardized materials.* Standardized materials and content are required materials and content that must be used in the form and manner provided by CMS.

(1) When CMS issues standardized material or content, a Part D sponsor must use the document without alteration except for the following:

(i) Populating variable fields.

(ii) Correcting grammatical errors.

(iii) Adding customer service phone numbers.

(iv) Adding plan name, logo, or both.

(v) Deleting content that does not pertain to the plan type (for example, removing MA language for a Part D plan).

(vi) Adding the SMID.

(vii) A Notice of Privacy Practices as required under the HIPAA Privacy Rule (45 CFR 164.520).

(2) When CMS issues standardized content, Part D sponsors—

(3) The Part D sponsor may develop accompanying language for standardized material or content, provided that language does not conflict with the standardized material or content. For example, CMS may issue standardized content associated with an appeal notification and Part D sponsor may draft a letter that includes the standardized content in the body of the letter; the remaining language in the letter is at the sponsor's discretion, provided it does not conflict with the standardized content or other regulatory standards.

(c) *Model materials.* Model materials and content are those required materials and content created by CMS as an example of how to convey beneficiary information. When drafting required materials or content based on CMS models, Part D sponsors:

(1) Must accurately convey the vital information in the required material or content to the beneficiary, although the Part D sponsor is not required to use CMS model materials or content verbatim; and

(2) Must follow CMS's specified order of content, when specified.

(d) *Delivery of required materials.* Part D sponsors must mail required materials in hard copy or provide them electronically, following the requirements in paragraphs (d)(1) and (2) of this section.

(1) For hard copy mailed materials, each enrollee must receive his or her own copy, except in cases of non-beneficiary-specific material(s) where the Part D sponsor has determined multiple enrollees are living in the same household and it has reason to believe the enrollees are related. In that case, the Part D sponsor may mail one copy to the household. The Part D sponsor must provide all enrollees an opt-out process so the enrollees can each receive his or her own copy, instead of a copy to the household. Materials specific to an individual beneficiary must always be mailed to that individual.

(2) Materials may be delivered electronically following the requirements

in paragraphs (d)(2)(i) and (ii) of this section.

(i) Without prior authorization from the enrollee, Part D sponsors may mail new and current enrollees a notice informing enrollees how to electronically access the following required materials: the Evidence of Coverage, Provider and Pharmacy Directories, and Formulary. The following requirements apply:

(A) The Part D sponsor may mail one notice for all materials or multiple notices.

(B) Notices for prospective year materials may not be mailed prior to September 1 of each year, but must be sent in time for an enrollee to access the specified materials by October 15 of each year.

(C) The Part D sponsor may send the notice throughout the year to new enrollees.

(D) The notice must include the website address to access the materials, the date the materials will be available if not currently available, and a phone number to request that hard copy materials be mailed.

(E) The notice must provide the enrollee with the option to request hardcopy materials. Requests may be material specific, and must have the option of a one-time request or a permanent request that must stay in place until the enrollee chooses to receive electronic materials again.

(F) Hard copies of requested materials must be sent within three business days of the request.

(ii) With prior authorization from the enrollee, the Part D sponsor may provide any required material or content electronically. To do so, the Part D sponsor must do all of the following:

(A) Obtain prior consent from the enrollee. The consent must specify both the media type and the specific materials being provided in that media type.

(B) Provide instructions on how and when enrollees can access the materials.

(C) Have a process through which an enrollee can request hard copies be mailed, providing the beneficiary with the option of a one-time request or a permanent request (which must stay in place until the enrollee chooses to receive electronic materials again), and

with the option of requesting hard copies for all or a subset of materials. Hard copies must be mailed within three business days of the request.

(D) Have a process for automatic mailing of hard copies when electronic versions or the chosen media type is undeliverable.

(e) *CMS required materials and content.* The following are required materials that must be provided to current and prospective enrollees, as applicable, in the form and manner outlined in this section. Unless otherwise noted or instructed by CMS and subject to § 423.2263(a) of this chapter, required materials may be sent once a fully executed contract is in place, but no later than the due dates listed for each material in this section.

(1) *Evidence of Coverage (EOC).* The EOC is a standardized communications material through which certain required information (under § 423.128(b)) must be provided annually and must be provided:

- (i) To current enrollees of plan by October 15, prior to the year to which the EOC applies.
- (ii) To new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(2) *Part D explanation of benefits (EOB).* The EOB is a model communications material through which plans must provide the information required under § 423.128(e). Part D sponsors must provide enrollees with an EOB no later than the end of the month following any month in which the enrollee utilized their prescription drug benefit.

(3) *Annual Notice of Change (ANOC).* The ANOC is a standardized marketing material through which plans must provide the information required under § 423.128(g)(2) annually.

- (i) Must send for enrollee receipt no later than September 30 of each year.
- (ii) Enrollees with an October 1, November 1, or December 1 effective date must receive within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(4) *Pre-enrollment checklist (PECL).* The PECL is a standardized commu-

nications material that plans must provide to prospective enrollees with the enrollment form, so that the enrollees understand important plan benefits and rules. For telephonic enrollments the contents of the PECL must be reviewed with the prospective enrollee prior to the completion of the enrollment. It references information on the following:

- (i) The EOC.
- (ii) Provider directory.
- (iii) Pharmacy directory.
- (iv) Formulary.
- (v) Premiums/copayments/coinsurance.
- (vi) Emergency/urgent coverage.
- (vii) Plan-type rules.
- (viii) Effect on current coverage.

(5) *Summary of Benefits (SB).* Part D sponsors must disseminate a summary of highly utilized coverage that include benefits and cost sharing to prospective enrollees, known as the SB. The SB is a model marketing material. It must be in a clear and accurate format.

(i) The SB must be provided with an enrollment form as follows:

- (A) In hardcopy with a paper enrollment form.
- (B) For online enrollment, the SB must be made available electronically (for example, via a link) prior to the completion and submission of enrollment request.
- (C) For telephonic enrollment, the beneficiary must be verbally told where the SB can be accessed.

(ii) The SB must include the following information:

- (A) Information on prescription drug expenses, including:
 - (1) Monthly plan premium
 - (2) Deductible, the initial coverage phase, coverage gap, and catastrophic coverage.

(3) A statement that costs may differ based on pharmacy type or status (for example, preferred/non-preferred, mail order, long-term care (LTC) or home infusion, and 30- or 90-day supply), when applicable.

(4) For dual eligible enrollees with differing levels of cost must state how cost sharing and benefits differ depending on the level of Medicaid eligibility.

(B) Plan sponsors may describe or identify other health related benefits in the SB.

(6) *Enrollment/Election form*. This is the model communications material through which plans must provide the information required under § 423.32(b).

(7) *Enrollment Notice*. This is a model communications material through which plans must provide the information required under § 423.32(d).

(8) *Disenrollment Notice*. This is a model communications material through which plans must provide the information required under § 423.36(b)(2).

(9) *Formulary*. This is a model communications material through which Part D sponsors must provide information required under § 423.128(b)(4).

(i) Must be provided to current enrollees of plan by October 15 of each year.

(ii) Must also provide to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(10) *Low Income Subsidy (LIS) Notice*. This is a model communications content through which Part D sponsors must notify potential enrollees of what their plan premium will be once they are eligible for Extra Help and receive the low-income subsidy.

(11) *Low Income Subsidy (LIS) Rider*. This is a model communications material provided to all enrollees who qualify for Extra Help. In the LIS Rider, the Part D sponsors must convey how much help the beneficiary will receive in the benefit year toward their Part D premium, deductible, and copayments provide to all beneficiaries who qualify for Extra Help.

(i) The LIS Rider must be provided at least once per year by September 30.

(ii) The LIS Rider must be sent to enrollees who qualify for Extra Help or have a change in LIS levels within 30 days of receiving notification from CMS.

(12) *Midyear Change Notification*. This is a model communications material through which plans must provide a notice to enrollees when there is a mid-year change in benefits or plan rules, under the following timelines:

(i) Notices of changes in plan rules, unless otherwise addressed elsewhere in the regulation, must be provided 30 days in advance.

(ii) National Coverage Determination (NCD) changes announced or finalized less than 30 days before effective date, a notification is required as soon as possible.

(iii) Midyear NCD or legislative changes must be provided no later than 30 days after the NCD is announced or the legislative change is effective.

(A) Plans may include the change in next plan mass mailing (for example, newsletter), provided it is within 30 days.

(B) The notice must also appear on the MA organization's website.

(13) *Non-renewal notice*. This is a standardized communications material through which plans must provide the information required under § 423.507.

(i) The Non-renewal Notice must be provided at least 90 calendar days before the date on which the nonrenewal is effective. For contracts ending on December 31, the notice must be dated October 2 to ensure national consistency in the application of Medigap Guaranteed Issue (GI) rights to all enrollees, except for those enrollees in Medicare-Medicaid Plans (MMPs) and special needs plans (SNPs). Information about non-renewals or service area reductions may not be released to the public, including the Non-renewal Notice in this section, until CMS provides notification to the plan.

(ii) The Non-renewal Notice must do all of the following:

(A) Inform the enrollee that the plan will no longer be offered and the date the plan will end.

(B) Provide information about any applicable open enrollment periods or special election periods or both (for example, Medicare open enrollment, non-renewal special election period), including the last day the enrollee has to make a Medicare prescription drug plan selection.

(C) Explain what the enrollee must do to continue receiving Medicare coverage and what will happen if the enrollee chooses to do nothing.

(D) As required under § 423.507(a)(2)(ii)(A), provide a CMS-approved written description of alternative MA plan, MA-PD plan, and PDP options available for obtaining qualified Medicare services within the beneficiary's region in the enrollee's notice.

(E) Specify when coverage will start after a new Medicare plan is chosen.

(F) List 1-800-MEDICARE contact information together with other organizations that may be able to assist with comparing plans (for example, SHIPs).

(G) Include the Part D sponsor's call center telephone number, TTY number, and hours and days of operation.

(14) *Part D Transition Letter*. This is a model communications material that must be provided to the beneficiary when they receive a transition fill for a nonformulary drug. The Part D Transition Letter must be sent within three days of adjudication of temporary transition fill.

(15) *Pharmacy Directory*. This is a model communications material through which Part D sponsors must provide the information required under § 423.128. The pharmacy directory must meet all of the following:

(i) Be provided to current enrollees by October 15 of the year prior to the applicable year.

(ii) Be provided to new enrollees within 10 calendar days from receipt of CMS confirmation of enrollment or by last day of month prior to effective date, whichever is later.

(iii) Be provided to current enrollees upon request, within three business days of the request.

(iv) Be updated any time the Part D sponsor becomes aware of changes.

(A) All updates to the online pharmacy directories must be completed within 30 days of receiving information requiring update.

(B)(1) Updates to hardcopy provider directories must be completed within 30 days.

(2) Hardcopy directories that include separate updates via addenda are considered up-to-date.

(16) *Prescription transfer letter*. This is a model communications material that must be sent when a Part D sponsor requests permission from an enrollee to fill a prescription at a different network pharmacy than the one currently being used by enrollee.

(17) *Star Ratings Document*. This is a standardized marketing material through which Star Ratings information is conveyed to prospective enrollees.

(i) The Star Ratings Document is generated through HPMS.

(ii) The Star Ratings Document must be provided with an enrollment form as follows:

(A) In hardcopy with a paper enrollment form.

(B) For online enrollment, made available electronically (for example, via a link) prior to the completion and submission of enrollment request.

(C) For telephonic enrollment, the beneficiary must be verbally told where they can access the Star Ratings Document.

(iii) New Part D sponsors that have no Star Ratings are not required to provide the Star Ratings Document until the following contract year.

(iv) Updated Star Ratings must be used within 21 calendar days of release of updated information on Medicare Plan Finder.

(v) Updated Star Ratings must not be used until CMS releases Star Ratings on Medicare Plan Finder.

(18) *Coverage Determination Notices*. This is a model communications material through which plans must provide the information under § 423.568.

(19) *Excluded Provider Notices*. This is a model communications material through which plans must notify enrollees when a provider they use has been excluded from participating in the Medicare program based on an OIG exclusion or the CMS preclusion list.

(20) *Notice of Denial of Medicare Prescription Drug Coverage*. This is a standardized material used to convey detailed descriptions of denied drug coverage and appeal rights.

(21) *Medicare Prescription Drug Coverage and Your Rights*. This is a standardized communications material used to convey a beneficiary's appeal rights when a drug cannot be filled at point-of-sale.

(22) *Medicare Part D Coverage Determination Request Form*. This is a model communications material used to collect additional information from a prescriber.

(23) *Request for Additional Information*. This is a standardized communications material used by the Part D sponsor to request a beneficiary obtain additional

information from the prescriber regarding a beneficiary's exception request.

(24) *Notice of Right to an Expedited Grievance*. This is a model communications material used to convey a Medicare beneficiary's rights to request that a decision be made on a grievance or appeal within a shorter timeframe.

(25) *Notice of Inquiry*. This is a model communications material from a prescription drug plan informing a beneficiary if a drug is covered by the formulary.

(26) *Notice of Case Status*. This is a model communications material used to inform a beneficiary of the denial of an appeal and additional appeal rights.

(27) *Request for Reconsideration of Medicare Prescription Drug Denial*. This is a model communications material used to inform the beneficiary of rights to an independent review of a Part D sponsor's decision.

(28) *Notice of Redetermination*. This is a model communications material used to convey instructions for requesting an appeal of an adverse coverage determination.

(29) *LEP Reconsideration Request Form*. This is a model communication used to request an appeal of a decision on an LEP by the independent review entity.

(30) *Request for Administrative Law Judge (ALJ) Hearing or Review of Dismissal*. This is a model communication used by an enrollee to request a hearing by the ALJ or a review of the IRE dismissal.

(31) *Appointment of Representative (AOR)*. This is a standardized material used to assign an individual to act on behalf of a beneficiary for the purpose of an appeal, grievance, or coverage determination.

(32) *Member ID card*. The member ID card is a model communications material that plans must provide to enrollees as required under § 423.128(d)(2). The member ID card—

(i) Must be provided to new enrollees within 10 calendars days from receipt of CMS confirmation of enrollment or by the last day of month prior to the plan effective date, whichever is later;

(ii) Must include the Part D sponsor's—

(A) Website address;

(B) Customer service number (the member ID card is excluded from the hours of operations requirement under § 423.2262(c)(1)(i)); and

(C) Contract/PBP number;

(iii) Must include, if issued for a preferred provider organization (PPO) and PFFS plan, the phrase “Medicare limiting charges apply.”;

(iv) May not use a member's Social Security number (SSN), in whole or in part;

(v) Must be updated whenever information on a member's existing card changes; in such cases an updated card must be provided to the member;

(vi) Is excluded from the translation requirement under paragraphs (a)(2) through (4) of this section; and

(vii) Is excluded from the 12-point font size requirement under paragraph (a)(1) of this section.

(33) *Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability)*.

(i) Prior to contract year 2026 marketing on September 30, 2025, the notice is referred to as the *Multi-language insert (MLI)*. This is a standardized communications material which states, “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.” in the following languages: Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese.

(A) Additional languages that meet the 5-percent service area threshold, as required under paragraph (a)(2) of this section, must be added to the MLI used in that service area. A plan may also opt to include in the MLI any additional language that do not meet the 5 percent service area threshold, where it determines that this inclusion would be appropriate.

(B) Except where otherwise provided in paragraph (e)(33)(i)(G) of this section, the MLI must be provided with all required materials under paragraph (e) of this section.

(C) The MLI may be included as a part of the required material or as a

standalone material in conjunction with the required material.

(D) When used as a standalone material, the MLI may include organization name and logo.

(E) When mailing multiple required materials together, only one MLI is required.

(F) The MLI may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

(G) At plan option for CY 2025 marketing and communications beginning September 30, 2024, the plan may use the model notice described in § 423.2267(e)(33)(ii) to satisfy the MLI requirements set forth in paragraph (e)(33)(i) of this section.

(ii) For CY 2026 marketing and communications beginning September 30, 2025, the required notice is referred to as the *Notice of availability of language assistance services and auxiliary aids and services (Notice of Availability)*. This is a model communications material through which MA organizations must provide a notice of availability of language assistance services and auxiliary aids and services that, at a minimum, states that the MA organization provides language assistance services and appropriate auxiliary aids and services free of charge.

(A) This notice of availability of language assistance services and auxiliary aids and services must be provided in English and at least the 15 languages most commonly spoken by individuals with limited English proficiency of the relevant State or States associated with the plan's service area and must be provided in alternate formats for individuals with disabilities who require auxiliary aids and services to ensure effective communication.

(B) If there are additional languages in a particular service area that meet the 5 percent service area threshold, described in paragraph (a)(2) of this section, beyond the languages described in paragraph (e)(33)(i) of this section, the notice of availability of language assistance services and auxiliary aids and services must also be translated into those languages. MA organizations may also opt to translate the notice in any additional languages that do not meet the 5-percent service

area threshold, where the MA organization determines that this inclusion would be appropriate.

(C) The notice must be provided with all required materials under paragraph (e) of this section.

(D) The notice may be included as a part of the required material or as a standalone material in conjunction with the required material.

(E) When used as a standalone material, the notice may include organization name and logo.

(F) When mailing multiple required materials together, only one notice is required.

(G) The notice may be provided electronically when a required material is provided electronically as permitted under paragraph (d)(2) of this section.

(34) *Federal Contracting Statement*. This is model content through which plans must convey that they have a contract with Medicare and that enrollment in the plan depends on contract renewal.

(i) The Federal Contracting Statement must include all of the following:

(A) Legal or marketing name of the organization.

(B) Type of plan (for example PDP).

(C) A statement that the organization has a contract with Medicare (when applicable, Part D sponsors may incorporate a statement that the organization has a contract with the State/Medicaid program).

(D) A statement that enrollment depends on contract renewal.

(ii) Part D sponsors must include the Federal Contracting Statement on all marketing materials with the exception of the following:

(A) Banner and banner-like advertisements.

(B) Outdoor advertisements.

(C) Text messages.

(D) Social media.

(E) Envelopes

(35) *Star Ratings Disclaimer*. This is model content through which plans must:

(i) Convey that plan sponsors are evaluated yearly by Medicare

(ii) Convey that the ratings are based on a 5-star rating system

(iii) Include the model content in disclaimer form or within the material whenever Star Ratings are mentioned

in marketing materials, with the exception of when Star Ratings are published on small objects (that is, a giveaway items such as a pens or rulers).

(36) *Accommodations Disclaimer.* This is model content through which plans must:

(i) Convey that accommodations for persons with special needs is available

(ii) Provide a telephone number and TTY number

(iii) Include the model content in disclaimer form or within the body of the material on any advertisement of invitation to all events as described under § 423.2264(c).

(37) *Mailing Statements.* This is standardized content. It consists of statements on envelopes that Part D sponsor must include when mailing information to current members, as follows:

(i) Part D sponsors must include the following statement when mailing information about the enrollee's current plan: "Important [Insert Plan Name] information."

(ii) Part D sponsors must include the following statement when mailing health and wellness information "Health and wellness or prevention information."

(iii) The Part D sponsor must include the plan name; however, if the plan name is elsewhere on the envelope, the plan name does not need to be repeated in the disclaimer.

(iv) Delegated or sub-contracted entities and downstream entities that conduct mailings on behalf of a multiple Part D sponsors must also comply with this requirement, however, they do not have to include a plan name.

(38) *Promotional Give-Away Disclaimer.* This is model content. The disclaimer consists of a statement that must make clear that there is no obligation to enroll in a plan, and must be included when offering a promotional give-away such as a drawing, prizes, or a free gift.

(39) *Provider Co-Branded Material Disclaimer.* This is model content through which Part D sponsors must:

(i) Convey, as applicable, that other pharmacies, physicians or providers are available in the plan's network.

(ii) Include the model content in disclaimer form or within the material

whenever co-branding relationships with network provider are mentioned.

(40) *Limited access to preferred cost-sharing pharmacies.* This is standardized content that must—

(i) Be used on all materials mentioning preferred pharmacies when there is limited access to preferred pharmacies; and

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

(41) *Third-party marketing organization disclaimer.* This is standardized content. If a TPMO does not sell for all Part D sponsors in the service area the disclaimer consists of the statement: "We do not offer every plan available in your area. Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. Please contact *Medicare.gov*, 1-800-MEDICARE, or your local State Health Insurance Program to get information on all of your options." If the TPMO sells for all Part D sponsors in the service area the disclaimer consists of the statement: "Currently we represent [insert number of organizations] organizations which offer [insert number of plans] products in your area. You can always contact *Medicare.gov*, 1-800-MEDICARE, or your local State Health Insurance Program for help with plan choices." The Part D sponsor must ensure that the disclaimer is as follows:

(i) Used by any TPMO, as defined under § 422.2260, that sells plans on behalf of more than one Part D sponsor.

(ii) Verbally conveyed within the first minute of a sales call.

(iii) Electronically conveyed when communicating with a beneficiary