Marketing Guidance for Massachusetts Medicare-Medicaid Plans

Contract Year (CY) 2023

Issued: July 13, 2022

Table of Contents

Introduction

All Medicare Advantage-Prescription Drug (MA-PD) plan sponsor requirements in 42 CFR Parts 422 and 423 as well as all MA-PD plan sponsor requirements in the Medicare Communications and Marketing Guidelines (MCMG), posted at www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines apply to Medicare-Medicaid Plans (MMPs) participating in the Massachusetts capitated financial alignment model demonstration, except as clarified or modified in this guidance document.[1] In addition, the Centers for Medicare and Medicaid Services (CMS) recently codified guidance on May 9, 2022,[2] which also applies to MMPs except as clarified in this document.

As defined in 42 CFR 422.2260 and 423.2260 prior to the implementation of the CMS-4182-F,[3] CMS continues to consider all Contract Year (CY) 2023 MMP materials to be marketing materials, including those that promote the organization or any MMP offered by the organization; inform beneficiaries that they may enroll or remain enrolled in an MMP offered by the organization; explain the benefits of enrollment in an MMP, or rules that apply to enrollees; and/or explain how services are covered under an MMP, including conditions that apply to such coverage.

This document provides information only about those sections or subsections of the regulations and MCMG that are not applicable or that are different for MMPs in Massachusetts. Information in this document is applicable to all marketing done for CY 2023 benefits.

Additional Guidance for Massachusetts MMPs

The following are additional Massachusetts MMP-specific modifications to the marketing regulations and MCMG:

Formulary and formulary change notice requirements

Massachusetts MMPs should refer to the November 1, 2018, CMS memorandum, "Part D Communication Materials," for guidance on formulary and formulary change notice requirements. As noted in that memorandum, additional updates to reflect changes related to 42 CFR 423.120(b)(5), regarding notice of mid-year formulary changes and changes to the definition of an approved month's supply, will be incorporated into the Medicare Prescription Drug Benefit Manual in a future release. In addition, we note that

---

[1] Note that any requirements for Special Needs Plans (SNPs), Private Fee-for-Service (PFFS) plans, Preferred Provider Organizations (PPOs), and Section 1876 Cost-Based Plans (cost plans) do not apply unless specifically noted in this guidance.

[2] Refer to Contract Year 2023 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency, which may be found in the Final Rule published on May 9, 2022 (https://www.federalregister.gov/documents/2022/05/09/2022-09375/medicare-program-contract-year-2023-policy-and-technical-changes-to-the-medicare-advantage-and).

[3] Refer to CMS-4182-F, Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE program, which may be found in the Final Rule published April 16, 2018 (www.federalregister.gov/documents/2018/04/16/2018-07179/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare, p. 16625).

Massachusetts MMPs are required to adhere to all new regulatory provisions and requirements.

The requirements of the November 1, 2018, CMS memorandum apply with the following modifications:

- Formulary change notices must be sent for any negative formulary change (as described in Chapter 6 of the Prescription Drug Benefit Manual), regardless of whether or not the negative formulary change applies to an item covered under Medicare or Medicaid, or as an additional drug benefit under the plan.

- Formulary change notices applicable to all formulary changes (not just Part D drug changes) must be maintained on Massachusetts MMP websites.

Informational and enrollment calls and scripts

We clarify that MMP customer service representatives may conduct activities that do not require the use of state-licensed marketing representatives. We also clarify that, to provide more than factual information, MMP outbound callers must be state-licensed (and, when required, appointed) marketing agents. Furthermore, MMPs must use a state-licensed (and, when required, appointed) marketing agent for any marketing activity.

Additionally, MMPs may not ask callers if they would like to receive information about other Medicare lines of business they offer. Such information may only be provided at the proactive request of a member.

We clarify that informational calls to plan call centers that become enrollment calls at the proactive request of the beneficiary must be transferred to the MassHealth customer service vendor. Enrollment scripts are not applicable to MMPs because all enrollment requests must be transferred to the MassHealth customer service vendor. We further clarify that telesales scripts are considered marketing, and MMPs must submit such scripts in the Health Plan Management System (HPMS) Marketing Review Module.

Marketing MMP and non-MMP offerings

We clarify that organizations offering both MMPs and non-MMP Medicare health plan options in a service area may only market MMP offerings in their MMP materials.

Disclosure Requirements, Provision of Specific Information, Call Centers

422.111, 422.111(h)

We clarify that hold time messages that include marketing content must be submitted in the HPMS Marketing Review Module.

Additionally, we clarify that MMPs must operate a toll-free call center during usual business hours. In light of the scope and nature of the services and benefits provided by MMPs, CMS interprets usual business hours for customer service call centers for both current and prospective enrollees as meaning at the following: seven (7) days a week, at least from 8 a.m. to 8 p.m. ET, except as provided below. Customer service call center hours and days must be the same for all individuals regardless of whether they speak English, a non-English language, or use assistive devices for communication. During this time period, current and prospective enrollees must be able to speak with a live customer service representative. MMPs may use

alternative technologies on Saturdays, Sundays, and federal holidays (with the exception of New Year's Day) in lieu of having living customer service representatives. For example, an MMP may use an interactive voice response (IVR) system or similar technologies to provide required information and allow individuals to leave a message (messages must be returned within one (1) business day). However, MMPs must provide live customer service during usual business hours for customer service calls on New Year's Day. We also clarify that the remainder of 422.111(h) applies to MMPs.

Reward and Incentive Programs

422.134

We clarify that MMPs may market rewards and incentives to current enrollees, consistent with the regulation. Additionally, we clarify that MMPs must:

- Promote engagement in specific behaviors (e.g., guideline-recommended clinical screenings and PCP visits and wellness initiatives) in reward and incentive programs.

- Take measures to monitor the effectiveness of such reward and incentive programs and revise incentives as appropriate, with consideration of enrollee feedback.

- Ensure that the nominal value of enrollee incentives does not exceed $15 per incentive or $75 aggregate annually, per individual.

- Submit to the Massachusetts Executive Office of Health and Human Services (EOHHS), at the direction of EOHHS, ad hoc report information relating to planned and implemented enrollee reward and incentive programs and ensure that all such programs comply with all applicable CMS and state guidance and all relevant state and federal laws.

Definitions

422.2260, 423.2260

MMPs are generally subject to marketing and beneficiary communications applicable to Medicare Advantage plans in 42 CFR Parts 422 and 423, as well as those applicable to Medicaid managed care organizations in 42 CFR Part 438. We clarify that the definitions of communications and marketing as described in these sections of the regulations are not applicable to MMPs. CMS continues to consider all CY 2023 MMP materials to be marketing materials as stated in the "Introduction" in this document. For any other references to communications throughout 42 CFR Parts 422 and 423, the definition of marketing materials applies, and we provide additional details about materials in the CMS Required Materials and Content (422.2267(e)) section of this document.

Submission, Review, and Distribution of Materials

422.2261, 423.2261

General requirements

422.2261(a), 423.2261(a)

We clarify that MMPs are required to submit all plan websites for review, including those that are limited to content required under 422.2265 using the process described in the Submission of Required Websites section of the MCMG.

CMS developed a Joint Review Process (JRP) for MMP materials under each Financial Alignment Initiative capitated model demonstration that combines state and CMS review requirements and parameters. Any references herein to CMS in its role in reviewing marketing materials are also references to the state for purposes of MMP marketing material review.

CMS review of marketing materials and election forms

422.2261(b), 423.2261(b)

We clarify that, for purposes of MMP materials, there is no "deeming" of materials requiring either a dual review by CMS and the state or a one-sided state review, and materials remain in a "pending" status until the state and CMS reviewer dispositions match. Materials that require a CMS-only review deem after the respective 10- or 45-day review period. MMPs may obtain more information about the specific review parameters and timeframes for marketing materials in the HPMS Marketing Review Module and User Guide.

We clarify that the File and Use certification process for MMPs is included in the three-way contract.

General Communications Materials and Activities Requirements

422.2262, 423.2262

We clarify that an MMP is a "comparable plan as determined by the Secretary" as described in 422.2262(a) and is available only to, designed for, and marketed to beneficiaries who are dually eligible for Medicare and Medicaid.

As is the case for other Medicare health plans, MMPs are required to include the plan type in each plan's name using standard terminology consistent with the guidance provided in this section. CMS created the standardized plan type label "Medicare-Medicaid Plan" to refer generically to all plans participating in a Financial Alignment Initiative captiated model demonstration. MMPs must include the "Medicare-Medicaid Plan" plan type terminology at the end of their plan name at least once on the front page or at the beginning of each marketing piece, excluding envelopes.

All MMPs are referred to by the standardized plan name type "(Medicare-Medicaid Plan)" in CMS external communications – e.g., the *Medicare & You* handbook and Medicare Plan Finder on www.medicare.gov. The state has provided guidance on branding for MMPs in Massachusetts, which includes using the term "One Care plan." Thus, we clarify that MMPs must use the CMS standardized plan type, "<Plan Name> (Medicare-Medicaid Plan)," once in

each marketing material, as indicated in the previous paragraph but may use the term “One Care plan” thereafter in the document.

To reduce beneficiary confusion, we also clarify that MMPs in Massachusetts that offer Medicare Advantage products, including Special Needs Plans (SNPs), in the same service area as their MMPs may not use the same plan marketing name for both of those products. Thus, for example, an organization offering both a SNP and an MMP in the same service area could not use the same name – e.g., Acme Duals Care (HMO SNP) – for its SNP product as for its MMP product – e.g., Acme Duals Care (Medicare-Medicaid Plan).

Product endorsements and testimonials

422.2262(b), 423.2262(b)

We further clarify these subsections of the regulations with additional guidance for Massachusetts MMPs. Product endorsements and testimonials for marketing purposes can aid beneficiaries in making informed decisions and, therefore, are not considered misleading when they adhere to the following:

- The speaker must identify the MMP’s product by name.
- A Medicare beneficiary endorsing or promoting an MMP or a specific product must be a current enrollee of that plan.
- If an individual is paid to endorse or promote the MMP or product, it 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.”
- An individual’s endorsement or testimonial cannot use any quotes by a physician or other health care provider.
- A contracted or employed physician or other health care provider cannot provide an endorsement or testimonial.
- An endorsement or testimonial cannot use negative testimonials about other Plans or Part D Sponsors.
- The MMP must be able to substantiate any claims made in the endorsement or testimonial.

Reusing individual user content or comments from social media sites (e.g., Facebook, Twitter) that promote an MMP’s product is considered an endorsement or testimonial and must adhere to the guidance in this subsection of the document.

Requirements when including certain telephone numbers in materials

422.2262(c), 423.2262(c)

In addition to the requirements of this section, MMPs must also provide the phone and TTY numbers and days and hours of operation information for MassHealth’s customer service

vendor at least once in any marketing materials that are provided prior to the time of enrollment and where a customer service number is provided for current and prospective enrollees to call. Use of the disclaimer in the "Unsolicited contact" subsection in this document is adequate to meet this requirement for unsolicited marketing materials, such as mail and other print media. Enrollment materials sent to passively enrolled individuals do not need to include the disclaimer.

Standardized Material Identification (SMID)

422.2262(d), 423.2262(d)

The provisions in these subsections of the regulations are modified as follows for MMPs:

> The SMID is made up of two parts: (1) MMP contract number (i.e., H number) followed by an underscore and (2) any series of alphanumeric characters chosen at the discretion of the MMP. Use of the material ID on marketing materials must be immediately followed by the status of either approved or accepted (e.g., H1234_drugx38 Approved). **Note:** MMPs should include an approved status only after the material is approved and not when submitting the material for review.

We clarify that multi-plan materials are not applicable to MMPs.

In addition, when a third party, such as a pharmacy benefit manager (PBM), creates and distributes member-specific materials on behalf of multiple organizations, it is not acceptable to use the material ID for another organization for materials the third party provides to MMP enrollees. The material must be submitted in HPMS using a separate material ID number for the MMP, and that material ID number must be included on the material. Non-English and alternate format materials based on previously created materials may have the same material ID as the material on which they are based.

General Marketing Requirements

422.2263, 423.2263

Plan comparisons

422.2263(b)(5), 423.2263(b)(5)

We further clarify these subsections of the regulations with additional guidance for Massachusetts MMPs. An MMP may not compare their plan to another Plan or Part D Sponsor by name without written concurrence from all Plans or Part D Sponsors being compared. The MMP must include this documentation with the material in the HPMS submission.

An MMP may compare their plan to another Plan or Part D Sponsor by referencing a study or statistical data. An MMP using a non-CMS study or survey in their marketing materials must include the following information, in text or as a footnote, on marketing pieces:

- Name of the organization sponsoring the study;
- Information about the MMP's relationship with the entity that conducted the study; and
- Publication title, date, and page number.

The MMP should also include this information in the HPMS marketing material transmittal comments field when submitting the document that includes the reference. Marketing reviewers may request additional information about the study or survey.

Star Ratings

422.2263(c), 423.2263(c)

MMPs are not subject to the Star Ratings requirements in these subsections of the regulations. Therefore, we clarify the provisions in these subsections do not apply to MMPs.

Beneficiary Contact

422.2264, 423.2264

Unsolicited contact

422.2264(a), 423.2264(a)

These subsections of the regulations provide examples of unsolicited direct contact with current and prospective enrollees. We reiterate that marketing via conventional mail and other print media (e.g., advertisements, direct mail) is not considered unsolicited contact and, therefore, is permissible.

In addition to the provisions of these subsections of the regulations, MMPs conducting permitted unsolicited marketing activities, such as through email (provided that they include an opt-out function), conventional mail and other print media, are required to include the following disclaimer on all materials used for that purpose:

> "For information on <Plan Name> and other options for your health care, call the MassHealth Customer Service Center at 1-800-841-2900, Monday through Friday, 8 a.m. - 5 p.m., (TTY: 1-800-497-4648), or visit www.mass.gov/eohhs/consumer/insurance/one-care/."

For purposes of these subsections of the regulations, enrollment materials sent to passively enrolled individuals are not considered marketing through unsolicited contact.

Contact for plan business

422.2264(b), 423.2264(b)

The requirements of these subsections of the regulations apply with the following clarifications and modifications:

- MMPs may not call current MMP enrollees to promote other Medicare plan types. Information about other Medicare plan types can only be provided at the proactive request of a current MMP enrollee.

- Organizations that offer non-MMP and MMP products may call their current non-MMP enrollees (e.g., those in Medicaid managed care products), including

individuals who have previously opted out of passive enrollment into an MMP, to promote their MMP offerings.

- Plans may use reasonable efforts to contact current non-MMP enrollees who are eligible for MMP enrollment to provide information about their MMP products. Callers with questions about other Medicare program options should be warm transferred to 1-800-MEDICARE or to the State Health Insurance Assistance Program (SHIP) for information and assistance.

Events with beneficiaries

422.2264(c), 423.2264(c)

Marketing or sales events

422.2264(c)(2), 423.2264(c)(2)

The provisions of these subsections of the regulations apply to Massachusetts MMPs with additional clarifications. If enrollment applications are distributed during the course of a marketing/sales event, any and all associated cover pages must remain attached to the application. If MMP customer service staff assist potential enrollees in filling out enrollment applications, the staff must direct the potential enrollee to first read any and all associated cover pages attached to the application. The staff must also read the cover page(s) aloud to the enrollee if asked. Plan customer service staff who assist in completing an application must document their name on the application in accordance with the application's instructions.

Personal marketing appointments

422.2264(c)(3), 423.2264(c)(3)

The provisions of these subsections of the regulations apply to Massachusetts MMPs, with the following modifications:

- MMP sales agents may not conduct unsolicited personal or individual appointments. To the extent an MMP offers individual appointments, trained customer service representatives must staff the appointments.

- An MMP can offer an individual appointment to a member who has contacted the MMP to request assistance or information. However, an MMP must not make unsolicited offers of individual appointments. An individual appointment must only be set up at the request of the member or their authorized representative

- An MMP must make reasonable efforts to conduct an appointment in the member's preferred location. An MMP cannot require that an individual appointment occur in a member's home.

In addition, the same clarifications in the "Marketing or sales events" subsection of this document apply to any enrollment application distributed during a personal or individual appointment.

Websites

422.2265, 423.2265

Required content

422.2265(b), 423.2265(b)

In addition to the requirements outlined in this section, MMPs must also include on their websites a direct link to the following website: www.mass.gov/one-care. MMPs must also include information on the potential for contract termination (as required under 42 CFR 422.111(f)(4)) and information that materials are published in alternate formats (e.g., large print, braille, audio).

We clarify that MMPs are not required to post the low-income subsidy (LIS) Premium Summary Chart as this document is not applicable to MMPs.

The provisions in these subsections of the regulations are modified for Massachusetts MMPs, in accordance with their three-way contracts, as follows:

> While MMPs are encouraged to have searchable, machine-readable formularies, MMPs must make their online directories available in a searchable, machine-readable file and format.

Required posted materials

422.2265(c), 423.2265(c)

The provisions of these subsections of the regulations apply with a modification. As indicated in 422.2263(c) and 423.2263(c) in the “Star Ratings” subsection of this document, MMPs are not subject to Star Ratings requirements and, therefore, are not required to post a CMS Star Ratings document on their websites.

Activities with Healthcare Providers or in the Healthcare Setting

422.2266, 423.2266

Provider-initiated activities

422.2266(c), 423.2266(c)

We clarify that the guidance in these subsections of the regulations about referring patients to other sources of information such as the “State Medicaid Office” also applies to materials produced by the state and/or distributed by the MassHealth customer service vendor.

Required Materials and Content

422.2267, 423.2267

We clarify that, unless otherwise modified and/or specifically indicated in this section of the document, these sections of the regulations, and all of their subsections, apply to MMPs.

Standards for required materials and content

422.2267(a)(2), 423.2267(a)(2)

The provisions of these subsections of the regulations apply with the modifications and clarifications included in this document. The standard articulated for translation of marketing materials into non-English languages is superseded to the extent that the Massachusetts standard for translation of marketing materials is more stringent. The Massachusetts translation standard, which requires translation of materials into "prevalent languages" (i.e., Spanish and any language that is the primary language of five (5) percent or more of the plan's service area population), typically exceeds the Medicare standard for translation in Massachusetts MMP service areas. Guidance on the translation requirements for all plans, including MMPs, is released annually each fall via HPMS. Required languages for translation for each MMP are also updated annually, as needed, in the HPMS Marketing Review Module. In addition, MMPs in Massachusetts must include statements in Cambodian, Chinese, Haitian Creole, Laotian, Portuguese, Spanish, Russian, and Vietnamese informing individuals of free language assistance services and contact phone and TTY numbers.

CMS and the state have designated materials that are vital and, therefore, must be translated into specified non-English languages.[4] This information is located in the CMS Required Materials and Content (422.2267(e)) section of this document.

MMPs must have a process for ensuring that enrollees can make a standing request to receive materials identified in this section, in alternate formats and in all non-English languages identified above and in the HPMS Marketing Review Module, at the time of request and on an ongoing basis thereafter. The process should include how the MMP will keep a record of the member's information and utilize it as an ongoing standing request so the member does not need to make a separate request for each material and how a member can change a standing request for preferred language and/or format.

[4] CMS makes available Spanish translations of the Massachusetts MMP SB, Formulary (List of Covered Drugs), Provider and Pharmacy Directory, and ANOC/EOC (Member Handbook). These are posted at www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPMarketingInformationandResources. CMS makes available a Spanish and Chinese translation of the Part D transition letter to all Medicare health plans at www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-D-Model-Materials.

Model materials

422.2267(c), 423.2267(c)

We modify these subsections of the regulations, in addition to 42 CFR Parts 417 and 438, with the following guidance about model materials.

We note that materials MMPs create should take into account the average reading level established in the three-way contract. Available models reflect acceptable average reading levels. Current Part D models are acceptable for use as currently provided, and MMPs must add required disclaimers included in the State-Specific MMP Disclaimers section of this document, as appropriate. Adding required MMP disclaimers to Part D models does not render the documents non-model when submitted for review or accepted as File and Use materials.

We refer MMPs to the following available models:

- MMP-specific model materials tailored to MMPs in Massachusetts, including an Annual Notice of Changes (ANOC), Summary of Benefits (SB), Evidence of Coverage (EOC) (Member Handbook), comprehensive integrated Formulary (List of Covered Drugs), Provider and Pharmacy Directory, single Member ID Card, welcome letters, Integrated Denial Notice, and notices of appeals decisions: www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPMarketingInformationandResources.

- Required Part D materials, including the Part D Explanation of Benefits, Excluded Provider Letter, Prescription Transfer Letter, and Transition Letter: www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Part-D-Model-Materials.

- Part D appeals and grievances models and notices (including those in the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance): www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev and www.cms.gov/Medicare/Appeals-and-Grievances/MedPrescriptDrugApplGriev/Forms.

- Part C appeals and grievances models and notices (including those in the Parts C & D Enrollee Grievances, Organization/Coverage Determinations and Appeals Guidance): www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG and www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Notices-and-Forms.

- MMP-specific ANOC/EOC (Member Handbook) errata model: www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-

Office/FinancialAlignmentInitiative/MMPInformationandGuidance/MMPMarketingInformationandResources.

CMS required materials and content

422.2267(e), 423.2267(e)

We clarify that required materials and instructions for Massachusetts MMPs are included below and replace the requirements in 422.2267(e) and 423.2267(e) unless otherwise specifically indicated. We further clarify that the Pre-Enrollment Checklist referenced in 422.2267(e)(4) and 423.2267(e)(4) and is not applicable to MMPs since the state's enrollment broker submits all enrollments. As stated in the "Introduction" in this document, CMS continues to consider all CY 2022 MMP materials to be marketing materials. As a result, MMPs submit all materials in HPMS. In addition, all large print written materials for individuals with visual impairments shall be in a font size no smaller than 18 point.

MMPs may enclose additional benefit and plan operation materials with required materials, unless specifically prohibited in instructions or prohibited as noted for each material. Additional materials must be distinct from required materials and must be related to the MMP in which the beneficiary enrolled.

Annual Notice of Changes (ANOC)	
To Whom Required:	Must be provided to current enrollees of plan, including those with October 1, November 1, and December 1 effective dates.
Timing:	• MMPs must send for enrollee receipt no later than September 30 of each year. (**Note**: ANOC must be posted on MMP website by October 15.) • Enrollees with October 1, November 1, and December 1 enrollment effective dates must receive the ANOC for the upcoming year by one (1) month after the effective date of enrollment but not later than December 15.
Method of Delivery:	Hard copy or electronically if enrollee has opted into receiving electronic version as permitted.
HPMS Timing and Submission:	• Refer to the HPMS Marketing Review Module and User Guide. • Must be submitted prior to mailing ANOCs.
Format Specification:	• Massachusetts MMP model required for current CY. • Standardized model; a non-model document is not permitted.
Guidance and Other Needed Information:	• Actual Mail Dates (AMDs) and number of recipients (not the number of ANOCs mailed) must be entered into HPMS within 15 days of mailing. This includes mail dates for alternate materials. MMPs that mail in waves should enter the AMD for each wave. MMPs may enter up to ten (10) waves of mailings. For instructions on meeting this requirement, refer to the "Manage Material AMD/Beneficiary Information" section of the HPMS Marketing Review Module and User Guide. (**Note:** For a single mailing to multiple recipients, MMPs should enter an AMD that reflects the number of recipients, not the number of ANOC/EOCs (Member Handbooks) mailed.) • Plans may include the following with the ANOC: o Summary of Benefits o Provider and Pharmacy Directory o EOC (Member Handbook) o Formulary (List of Covered Drugs) o Notification of Electronic Documents • No additional plan communications unless otherwise directed.
Translation Required:	Yes.

ANOC and EOC (Member Handbook) Errata	
To Whom Required:	Must be provided when plan errors are found in the ANOC or EOC (Member Handbook) and sent to current enrollees.
Timing:	Must send to enrollees immediately following CMS approval.
Method of Delivery:	Hard copy or electronically if enrollee has opted into receiving electronic version as permitted.
HPMS Timing and Submission:	• Refer to the HPMS Marketing Review Module and User Guide. • ANOC errata must be submitted by October 15. • EOC (Member Handbook) errata must be submitted by November 15.
Format Specification:	Standardized model; a non-model document is not permitted.
Guidance and Other Needed Information:	MMPs must use an errata notice to notify enrollees of plan errors in their original documents. We clarify that errata notices should only be used to notify enrollees of plan errors in plan materials. **Note:** Any mid-year changes, including but not limited to mid-year legislative benefit additions or removals and changes in enrollment policies, should be communicated to current enrollees consistent with the "Mid-Year Change Notification" guidance in this section. The HPMS errata submission process should not be used for mid-year changes to materials that are not due to plan error. Instead plans should use the HPMS marketing module replacement function for these changes. Refer to the annual Health Plan Management System memo "Issuance of Contract Year Model Materials" and "Contract Year Annual Notice of Change and Evidence of Coverage Submission Requirements and Yearly Assessment" memos.
Translation Required:	Yes.

Comprehensive Medication Review Summary	
To Whom Required:	Provided to enrollees in a plan's Medication Therapy Management (MTM) program after receiving a comprehensive medication review (CMR)
Timing:	May be provided to enrollee immediately following a CMR, or if distributed separately, materials should be sent out within 14 calendar days.
Method of Delivery:	Hard copy or electronically if enrollee has opted into receiving electronic version as permitted.
HPMS Timing and Submission:	Not applicable.
Format Specification:	Standardized OMB-approved Format (Form CMS-10396, OMB Control Number 0938-1154). The format cannot be modified, but the specific content to populate the Format must be tailored to address issues unique to the individual enrollee and may be customized for the Part D plan and MTM program.
Guidance and Other Needed Information:	See https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM for CMR Standardized Format and detailed Implementation instructions and Annual MTM Program Submission Instructions memo. **Note:** MTM program materials should not include any marketing or promotional messages.
Translation Required:	Yes.

Coverage/Organization Determination, Discharge, Appeals and Grievance Notices	
To Whom Required:	• Must be provided to enrollees who have requested an appeal or have had an appeal requested on their behalf. • Grievances may be responded to electronically, orally, or in writing.
Timing:	Provided to enrollees (generally by mail) on an ad hoc basis, based on required timeframes in three-way contract.
Method of Delivery:	Hard copy or electronically, if enrollee has opted into receiving electronic version as permitted.
HPMS Timing and Submission:	Refer to the HPMS Marketing Review Module and User Guide.
Format Specification:	• Massachusetts MMP models - standardized model; a non-model document is not permitted. • Other CMS models - modifications permitted.
Guidance and Other Needed Information:	Three-way contract, Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance.
Translation Required:	Yes.

Evidence of Coverage (EOC)/Member Handbook	
To Whom Required:	Must be provided to all enrollees of plan.
Timing:	• Must send to current enrollees of plan for receipt by October 15 of each year. Must be posted on plan website by October 15 of each year. • Must send to enrollees who opt in to the MMP for receipt no later than ten (10) calendar days from receipt of CMS confirmation of enrollment or by last day of the month prior to the effective date, whichever is later. • Must send to enrollees who are passively enrolled for receipt by the end of the month preceding the month the enrollment will take effect (e.g., must be received by a beneficiary by March 31 for an April 1 effective enrollment date). • New enrollees with an effective date of October 1, November 1, or December 1 should receive both an EOC (Member Handbook) for the current CY, as well as an EOC (Member Handbook) document for the upcoming CY. We clarify that, for these members, the ANOC may be included in the EOC (Member Handbook) or provided separately, as well as the Formulary (List of Covered Drugs) (or a distinct and separate notice alerting enrollees how to access or receive the Formulary), and the Provider and Pharmacy Directory (or a distinct and separate notice alerting enrollees how to access or receive the directory) for the upcoming year, must be received by one (1) month after the effective date of enrollment, but not later than December 15.
Method of Delivery:	Hard copy EOC (Member Handbook) or via Electronic Notice of Documents, or electronically if enrollee has opted into receiving electronic version as permitted.
HPMS Timing and Submission:	• Refer to the HPMS Marketing Review Module and User Guide. • Submitted prior to October 15 of each year.
Format Specification:	• Massachusetts MMP model required for current CY. • Standardized model; a non-model document is not permitted.
Guidance and Other Needed Information:	No additional information.
Translation Required:	Yes.

Excluded Provider Letter	
To Whom Required:	Provided to enrollees when a sponsor has excluded a prescriber or pharmacy participating in the Medicare program based on an Office of Inspector General (OIG) exclusion.
Timing:	Provided to enrollees on an ad hoc basis.
Method of Delivery:	Hard copy, or electronically, if enrollee has opted into receiving electronic version as permitted.
HPMS Timing and Submission:	Refer to the HPMS Marketing Review Module and User Guide.
Format Specification:	Model provided; modifications permitted.
Guidance and Other Needed Information:	oig.hhs.gov/exclusions/index.asp.
Translation Required:	Yes.

Explanation of Benefits (EOB) – Part D	
To Whom Required:	Must be provided anytime an enrollee utilizes their prescription drug benefit.
Timing:	Sent at the end of the month following the month when the benefit was utilized.
Method of Delivery:	Hard copy or electronically if enrollee has opted into receiving electronic version as permitted.
HPMS Timing and Submission:	Refer to the HPMS Marketing Review Module and User Guide.
Format Specification:	Part D EOB model - modifications permitted.
Guidance and Other Needed Information:	Three-way contract and 423.2267(e)(2).
Translation Required:	Yes.

Formulary (List of Covered Drugs)	
To Whom Required:	Must be provided to all enrollees of plan.
Timing:	• Must be sent to current enrollees of plan for receipt by October 15 of each year. Must be posted on plan website by October 15 of each year. • Must send to enrollees who opt in to the MMP for receipt no later than ten (10) calendar days from receipt of CMS confirmation of enrollment or by last day of the month prior to the effective date, whichever is later. • Must send to enrollees who are passively enrolled for receipt no later than 30 calendar days prior to enrollment.
Method of Delivery:	Hard copy or via Electronic Notice of Documents, or electronically if enrollee has opted into receiving electronic version as permitted.
HPMS Timing and Submission:	Refer to the HPMS Marketing Review Module and User Guide.
Format Specification:	Standardized model; a non-model document is not permitted.
Guidance and Other Needed Information:	• MMPs must make available a comprehensive integrated Formulary (List of Covered Drugs) that includes Medicare and Medicaid outpatient prescription drugs and pharmacy products provided under the plan. • OTC items and/or supplemental benefits that are in excess of Medicaid requirements may not be included in this document. • MMPs are only permitted to make available a comprehensive, not abridged, Formulary (List of Covered Drugs).
Translation Required:	Yes.

Integrated Denial Notice	
To Whom Required:	Any enrollee with an adverse benefit determination.
Timing:	Provided to enrollees (generally by mail) on an ad hoc basis, at least 10 (ten) days in advance of any adverse benefit determination.
Method of Delivery:	Hard copy, or electronically, if enrollee has opted into receiving electronic version as permitted.
HPMS Timing and Submission:	Refer to the HPMS Marketing Review Module and User Guide.
Format Specification:	• Massachusetts MMP model required for current CY. • Standardized model; a non-model document is not permitted.
Guidance and Other Needed Information:	Three-way contract.
Translation Required:	Yes.

Member ID Card	
To Whom Required:	Must be provided to all plan enrollees.
Timing:	• Must send to enrollees who opt in to the MMP for receipt no later than ten (10) calendar days from receipt of CMS confirmation of enrollment or by last day of the month prior to the effective date, whichever is later. • Must send to enrollees who are passively enrolled for receipt by the end of the month preceding the month the enrollment will take effect (e.g., must be received by a beneficiary by March 31 for an April 1 effective enrollment date). • Must also be provided to all enrollees if information on existing card changes.
Method of Delivery:	Must be provided in hard copy. In addition to hard copy, MMPs may provide a digital version (e.g., app).
HPMS Timing and Submission:	Refer to the HPMS Marketing Review Module and User Guide.
Format Specification:	Standardized model; a non-model document is not permitted.
Guidance and Other Needed Information:	• MMPs must issue a single Member ID Card meeting these requirements for all services offered under the plan. • Separate pharmacy and health benefits Member ID cards are not permitted. • Must include MMP's website address, customer service number, and contract/plan benefit package number. • May not use social security number (SSN). • The front of the card must include the Medicare Prescription Drug Benefit Program Mark.
Translation Required:	No.

Mid-Year Change Notification to Enrollees	
To Whom Required:	Must be provided to all applicable enrollees when there is a mid-year change in benefits, plan rules, formulary, provider network, or pharmacy network.
Timing:	Ad hoc, based on specific requirements for each issue as defined in 422.2267(e)(9).
Method of Delivery:	Hard copy or electronically if enrollee has opted into receiving electronic version as permitted. If the mid-year change affects a document that the MMP has not sent to the member in hard copy (e.g., the EOC (Member Handbook)), the MMP is not required to send a hard copy mid-year change notification.
HPMS Timing and Submission:	Refer to the HPMS Marketing Review Module and User Guide.
Format Specification:	Model not available; must include required content.
Guidance and Other Needed Information:	• Notices of changes in MMP rules unless otherwise addressed in a regulation must be provided 30 days in advance. • National Coverage Determination (NCD) changes announced or finalized less than 30 days before effective date, notification required as soon as possible. • Mid-year NCD or legislative changes must be published no later than 30 days after the NCD is announced. MMPs may include change in the next plan mass mailing (e.g., newsletter), provided it is within 30 days and must be reflected on their website. • Medicare Managed Care Manual - Chapter 4. • Medicare Prescription Drug Benefit Manual - Chapter 6 and forthcoming guidance effectuating 423.120(b)(5) on formulary changes and required notice to beneficiaries and other entities. • National Coverage Determination website.
Translation Required:	Yes.

Non-Renewal and Termination Notices	
To Whom Required:	Must be provided to each affected enrollee after MMP decides to non-renew or reduce its plan's service area or before the termination effective date.
Timing:	At least 90 days before the end of the current contract period.
Method of Delivery:	Notices must be hard copy and sent via U.S. mail. First class postage is recommended.
HPMS Timing and Submission:	Refer to the HPMS Marketing Review Module and User Guide.
Format Specification:	• Massachusetts MMP model required for current CY. • Modifications permitted per instructions.
Guidance and Other Needed Information:	• Information about non-renewals or service area reductions may not be released to the public, including current enrollees, until notice is received from CMS and the state. • MMPs may elect to share Non-Renewal and Service Area Reduction (NR/SAR) information only with first tier, downstream, and related entities (FDRs) or anyone that the MMP does business with (i.e., contracted providers). • MMPs must provide a NR/SAR notice to beneficiaries who enroll in a non-renewing plan on October 1, November 1, or December 1 of the current contract year (e.g., less than 90 days before the effective date of the non-renewal). • Additional NR/SAR notice information can be found in the annual CMS memorandum, "Non-Renewal and Service Area Reduction Guidance and Enrollee Notification Models." • For terminations, relevant notice requirements are provided in 42 CFR 422.506, 422.508, and 422.512.
Translation Required:	Yes.

Part D Transition Letter	
To Whom Required:	Must be provided when a beneficiary receives a transition fill for a non-formulary drug.
Timing:	Must be sent within three (3) days of adjudication of temporary transition fill.
Method of Delivery:	Hard copy.
HPMS Timing and Submission:	Refer to the HPMS Marketing Review Module and User Guide.
Format Specification:	Model provided; modifications permitted.
Guidance and Other Needed Information:	Medicare Prescription Drug Benefit Manual, Chapter 6.
Translation Required:	Yes.

Prescription Transfer Letter	
To Whom Required:	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.
Timing:	Ad hoc.
Method of Delivery:	Hard copy.
HPMS Timing and Submission:	Refer to the HPMS Marketing Review Module and User Guide.
Format Specification:	Part D model provided; modifications permitted.
Guidance and Other Needed Information:	The MMP uses the model notice only when the transfer of the prescription is not initiated by the beneficiary (or someone on their behalf).
Translation Required:	Yes.

Provider and Pharmacy Directory	
To Whom Required:	Must be provided to all current enrollees of the plan.
Timing:	• Must be sent to current enrollees of Plan for receipt by October 15 of each year. Must be posted to plan website by October 15 of each year. • Must send to enrollees who opt in to the MMP for receipt no later than ten (10) calendar days from receipt of CMS confirmation of enrollment or by last day of the month prior to the effective date, whichever is later. • Must send to enrollees who are passively enrolled for receipt no later than 30 calendar days prior to enrollment. • Must be provided to current enrollees upon request, within three (3) business days of the request. • Must update directory information any time they become aware of changes. All updates to the online provider and pharmacy directories are expected to be completed within 30 days of receiving information. Updates to hard copy provider and pharmacy directories must be completed within 30 days; however, hard copy directories that include separate updates via addenda are considered up-to-date.
Method of Delivery:	Hard copy or via Electronic Notice of Documents, or electronically if enrollee has opted into receiving electronic version as permitted.
HPMS Timing and Submission:	Refer to the HPMS Marketing Review Module and User Guide.
Format Specification:	• Massachusetts MMP model required for current CY. • Standardized model; a non-model document is not permitted.

Provider and Pharmacy Directory	
Guidance and Other Needed Information:	• MMPs are required to make available a single combined Provider and Pharmacy Directory. Separate pharmacy and provider directories are not permitted. MMPs may print separate directories for primary care physicians (PCPs) and specialists provided both directories are made available to enrollees at the time of enrollment. • The single combined Provider and Pharmacy Directory must include all network providers and pharmacies, regardless of whether they provide Medicare, Medicaid, or additional benefits. • For MMPs with multi-county service areas, the combined Provider and Pharmacy Directory may be provided for all providers by county, provided the directory includes a disclaimer that the directory only includes providers in that particular county (or counties), that a complete directory is available on the plan's website, and that the enrollee may contact the plan's customer service call center to request assistance with locating providers in other counties or to request a complete hard copy Provider and Pharmacy Directory. • Massachusetts MMPs must submit directory updates and/or addenda pages in HPMS, and these documents are reviewed consistent with the parameters for the Massachusetts MMP Provider and Pharmacy Directory. • As applicable, refer to the language and guidelines in the CMS memorandum, dated August 16, 2016, "Pharmacy Directories and Disclaimers" for the pharmacy portion of the combined directory.
Translation Required:	Yes.

Safe Disposal Information	
To Whom Required:	Provided to enrollees in a plan's MTM program as part of the CMR, targeted medication review, or other MTM correspondence or service.
Timing:	At least once annually beginning on January 1, 2022.
Method of Delivery:	Hard copy or via Electronic Notice of Documents, or electronically if enrollee has opted into receiving electronic version as permitted in 422.2267(d) and 423.2267(d).
HPMS Timing and Submission:	Not applicable.
Format Specification:	No model required. This information must comply with all requirements of 422.111(j).
Guidance and Other Needed Information:	See www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM for Annual MTM Program Submission Instructions memo.
Translation Required:	Yes.

Scope of Appointment (SOA)	
To Whom Required:	Must be documented for all marketing activities, in-person, telephonically, including walk-ins to MMP or agent offices.
Timing:	Prior to the appointment.
Method of Delivery:	Beneficiary signed hard copy, telephonic recording, or electronically signed.
HPMS Timing and Submission:	Refer to the HPMS Marketing Review Module and User Guide.
Format Specification:	No model required; must include required content.

Guidance and Other Needed Information:	• The following requirements must be on the scope of appointment (SOA) form or on the recorded call:
	  ○ Product types to be discussed
	  ○ Date of appointment
	  ○ Beneficiary and agent contact information
	  ○ Statement stating no obligation to enroll, current or future Medicare enrollment status will not be affected, and automatic enrollment will not occur.
	• A new SOA is required if, during an appointment, the beneficiary requests information regarding a different plan type than previously agreed upon.

Translation Required:	Yes.

Summary of Benefits	
To Whom Required:	Enrollees who are passively enrolled. Optional with the ANOC and as requested for other enrollees.
Timing:	• Must send to enrollees who are passively enrolled for receipt no later than 30 calendar days prior to enrollment. • Must be available by October 15 of each year, but can be released as early as October 1 of each year. Must be posted on MMP website by October 15 of each year.
Method of Delivery:	Hard copy.
HPMS Timing and Submission:	• Refer to the HPMS Marketing Review Module and User Guide. • Submitted prior to October 15 of each year.
Format Specification:	• Massachusetts MMP model required for current CY. • Standardized model; a non-model document is not permitted.
Guidance and Other Needed Information:	The SB must contain a concise description of the important aspects of enrolling in the plan, as well as the benefits offered under the plan, including applicable copays, applicable conditions and limitations, and any other conditions associated with receipt or use of benefits.
Translation Required:	Yes.

Welcome Letter	
To Whom Required:	Must be provided to all new enrollees of MMP.
Timing:	• Must send to enrollees who opt in to the MMP for receipt no later than ten (10) calendar days from receipt of CMS confirmation of enrollment or by last day of the month prior to the effective date, whichever is later. • Must send to enrollees who are passively enrolled for receipt no later than 30 calendar days prior to enrollment.
Method of Delivery:	Hard copy.
HPMS Timing and Submission:	Refer to the HPMS Marketing Review Module and User Guide.
Format Specification:	Massachusetts MMP model required for CY.
Guidance and Other Needed Information:	• Must contain 4Rx information consistent with the model. • National Enrollment/Disenrollment Guidance for States and MMPs, section 30.5.1.
Translation Required:	Yes.

Required materials for new MMP enrollees

The following tables summarize the required materials, and timing of receipt, for new MMP enrollees.

Table 1: Required Materials for New Members – Passive Enrollment

Enrollment Mechanism	Required Materials for New Members	Timing of Beneficiary Receipt
Passive enrollment	• Welcome letter • Formulary (List of Covered Drugs) (or a distinct and separate notice alerting enrollees how to access or receive the formulary) • Provider and Pharmacy Directory (or a distinct and separate notice alerting enrollees how to access or receive the directory) • SB	30 calendar days prior to the effective date of enrollment
Passive enrollment	• Member ID Card • EOC (Member Handbook) (or a distinct and separate notice alerting enrollees how to access or receive the EOC)	No later than the day prior to the effective date of enrollment

Table 2: Required Materials for New Members – Opt-in Enrollment

Enrollment Mechanism	Required Materials for New Members	Timing of Beneficiary Receipt
Opt-in enrollment (with enrollment confirmation received more than ten (10) calendar days before the end of the month)[5]	• Welcome letter • Formulary (List of Covered Drugs) (or a distinct and separate notice alerting enrollees how to access or receive the formulary) • Provider and Pharmacy Directory (or a distinct and separate notice alerting enrollees how to access or receive the directory) • Member ID Card • EOC (Member Handbook) (or a distinct and separate notice alerting enrollees how to access or receive the EOC)	No later than the last day of the month prior to the effective date
Opt-in enrollment (with enrollment confirmation received less than ten (10) calendar days before the end of the month)[5]	• Welcome letter • Formulary (List of Covered Drugs) (or a distinct and separate notice alerting enrollees how to access or receive the formulary) • Provider and Pharmacy Directory (or separate notice alerting enrollees how to access or receive the directory) • Member ID Card • EOC (Member Handbook) (or a distinct and separate notice alerting enrollees how to access or receive the EOC)	No later than ten (10) calendar days from receipt of the CMS confirmation of enrollment

[5] We clarify that this group of enrollees who opt in includes individuals who are eligible for passive enrollment but select a different MMP or initiate an earlier enrollment date than their passive enrollment effective date. MMPs should refer to the date of the Daily Transaction Reply Report (DTRR) that has the notification to identify the start of the ten (10) calendar-day timeframe.

State-specific MMP Disclaimers

We clarify that MMPs include specific disclaimer language in the table below. We also clarify that, as applicable, MMPs include additional disclaimers contained in subsections 422.2267(e) and 423.2267(e) of the regulations. In addition, we clarify that MMPs are not required to include disclaimers on the following material types: Member ID Cards, call scripts not related to sales or enrollment, banners and banner-like ads, envelopes, outdoor advertising, text messages, and social media.

Disclaimer	Required MMP Disclaimer Language	MMP Disclaimer Instructions
Federal Contracting	<Plan's legal or marketing name> is a health plan that contracts with both Medicare and MassHealth (Medicaid) to provide benefits of both programs to enrollees.	Required on materials except those specifically excluded above
Benefits – "This is not a complete list…"	This is not a complete list. The benefit information is a brief summary, not a complete description of benefits. For more information contact the plan or read the <plan name> Member Handbook.	Required on the SB and all materials with ten (10) or more benefits except the Member Handbook (EOC)
Multi-language insert	ATTENTION: If you speak <language of disclaimer>, language assistance services, free of charge, are available to you. Call <Member Services toll-free phone and TTY numbers, and days and hours of operation>. The call is free.	Per 422.2267(e)(31) required in Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese and applicable non-English languages in those models in the CMS Required Material and Content section for which the last row of the table indicates, "*Translation required:* Yes"
Non-plan and Non-health Information	Neither Medicare nor MassHealth (Medicaid) has reviewed or endorsed this information.	Required on non-plan and non-health related information once prior authorization from the enrollee is granted to receive materials
Unsolicited Marketing Materials	For information on <Plan name> and other options for your health care, call the MassHealth Customer Service Center at 1-800-841-2900, Monday through Friday, 8 a.m. - 5 p.m., (TTY: 1-800-497-4648), or visit www.mass.gov/eohhs/consumer/insurance/one-care/.	Required when conducting permitted unsolicited marketing activities such as conventional mail and other print media

Note: For model materials, MMPs must continue to include disclaimers where they currently appear in the models. For non-model materials, MMPs may include disclaimers as footnotes or incorporate them into the body of the material.

Agent, Broker, and Other Third Party Requirements

422.2274, 423.2274

We clarify that Massachusetts does not permit the use of independent agents and brokers. The state's enrollment broker processes all MMP enrollments. We also clarify that CMS does not regulate compensation of employed agents. Employed MMP staff conducting marketing activity of any kind, as defined in this document, must be licensed in the state (and, when required, appointed) as an insurance agent or broker.

Additionally, we clarify reporting responsibilities for MMPs. Annually by the last Friday in July, MMPs must enter information in HPMS and attest to their intention to use agents or brokers in the upcoming plan year. MMPs must report their use of employed, captive, or independent agents or brokers in accordance with Massachusetts and CMS guidelines. For further instructions, refer to the *Agent/Broker Compensation* sections of the HPMS Marketing Review Module and User Guide. Following the reporting deadline, MMPs may not change their decisions related to agent or broker type until the next plan year.

The remainder of 422.2274 and 423.2274 does not apply to MMPs.

Appendix 1. Standardized Pre-Enrollment Checklist

This appendix does not apply to MMPs since all enrollments are submitted by the Massachusetts enrollment broker.

Appendix 2. Model Summary of Benefit Instructions

This appendix does not apply to MMPs in Massachusetts since they are required to use the model developed for the demonstration.

Appendix 3. Employer/Union Group Health Plans

This appendix does not apply to MMPs in Massachusetts.

Appendix 4. Use of Medicare Mark for Part D Sponsors

We clarify that MMPs have been required to sign a licensing agreement to use the official Medicare Mark as part of the three-way contract rather than through the HPMS contracting module. All other guidance in Appendix 4 of the MCMG applies.