Submission, Review, and Distribution of Materials (42 CFR §§ 422.2261, 423.2261)

§§ 422.2261(a), 423.2261(a) - General requirements

• *All marketing* materials, election forms, and certain designated communications materials used by a plan, including those used by third-party and downstream entities, must be submitted to CMS for review.

§§ 422.2261(a)(1), 423.2261(a)(1) – The HPMS Marketing Module is the primary system of record for the collection, review, and storage of materials that must be submitted for CMS review

- In limited situations and with prior approval from CMS, plans may submit materials outside of HPMS.
- Non-English/Alternate Format Materials
 - Plans are not required to submit non-English language materials that are translations of a previously submitted English version. The English Version of the Standardized material identification (SMID) may be used on non-English translations.
 - If a plan creates a material to be used only in a non-English language, the plan must submit an English translation to HPMS via a zip file containing both the material and the translations.
 - Plans are not required to submit alternate format versions of a previously submitted standard material.
- Submission of Required Websites –Websites that plans are required to maintain pursuant to 42 CFR §§ 422.2265 and 423.2265 do not require submission if they are limited to only providing the content and materials required under 42 CFR §§ 422.2265(b), 423.2265(b), 422.2265(c), and 423.2265(c). Required websites that contain additional marketing content must be submitted to CMS on an annual basis (contract year). Submission is done by selecting "Plan Required Website" under the "CMS Required" section of the HPMS Marketing Module. Regardless of submission, websites must include the current Material ID on all web pages. The following outlines how applicable websites must be submitted.
 - Each Contract Year's initial website submission must use a Microsoft Word document (or similar) listing the items on the website and must contain the website's URL. Screenshots, test sites, etc. are not needed. The Standardized Material Identification (SMID) used for the submission must correspond to the material ID on the website, except it will end with an underscore followed by the contract year (e.g., H1234_abcwebsite_M_2022). The contract year is not required on the actual webpages.
 - Updates made to the website for the same contract year, must be submitted using a Microsoft Word document (or similar) containing the URL and a list of all changes. The same material ID on the site's pages are permitted (e.g. H1234_abcwebsite_M). However, updated submissions must use the website's material ID followed by an underscore and contract year, followed by an underscore and a letter ("A", "B", "C", etc.) corresponding to each

- resubmission (e.g., H1234_abcwebsite_M_2020_A). The contract year and the letter do not have to be shown on the actual website.
- Plans are not required to submit web page updates when only communication content or content required in 42 CFR §§ 422.2265, 423.2265 has been updated.
- As outlined under §§ 422.2261(b)(3) and 423.2261(b)(3), plans must wait five (5) days following the submission of a website or website change(s) before going live with the website. However, plans are not required to take down their website while they are making updates.

§§ 422.2261(a)(3), 423.2261(a)(3) – Third-party submissions

Consultant Submitted Multi-Plan Marketing Materials - CMS permits third parties to submit marketing materials directly to CMS, on behalf of contracted plans, when the marketing materials created by a third party include marketing content of and used by multiple (two or more) plans. For example, if the third party operates a website that lists all contracted plans and their cost sharing, and is used by beneficiaries to select and enroll into a plan, the third party may submit the website on behalf of the contracted plans.

Note: The multi-plan submission process is intended for third parties that submit for multiple organizations. If the third party's marketing materials only mention one organization, then the plan should submit the material directly to CMS using the standard submission process.

Providing Consultant Access – The following steps are for third-party access to the HPMS marketing module for multi-plan submissions.

• Prepare an official letter that states the user's name, CMS user ID, consultant company name, the type of consultant access being requested, and the contract/multi-contract entity (MCE) number(s) for which consultant access is needed. The letter must be provided on the organization's official letterhead and signed by a senior official of the organization. Organizations can submit one letter and include multiple consultants on that letter if they are all obtaining the same consulting access type. CMS recommends the use of the following sample language:

(Name of organization) hereby requests that (name of consultant user, the CMS user ID, and consultant company name) be granted Marketing Consultant Access for Multi-Plan Submissions for the following contract number(s): (list specific contract numbers or provide the MCE number).

- Submit the official letter via e-mail in scanned PDF format to HPMSConsultantAccess@cms.hhs.gov. To facilitate timely processing, please indicate the type of consultant access in the subject line of the e-mail. It is a best practice for the plan to cc the third-party for which they are requesting access.
- An email confirmation will be provided to all included in the original e-mail (sender and all cc'd) when access has been granted. Unless the third-party was cc'd on the original e-mail request, plans are responsible for informing the third-party that the access has been approved.
- It is important to note that consultant user access is limited in HPMS to only the multiplan portion of the marketing module. Third parties cannot see or access other plan

- related marketing information outside of multi-plan submissions.
- For more information, please refer to the May 26, 2021 HPMS memo, "Updated Instructions for Requesting Consultant Access to the Health Plan Management System (HPMS)."

Note: Ultimately, it is the responsibility of the plan to manage and maintain the set of users for whom they have authorized access to HPMS. User access can be viewed under the "User Resources > User Access Administration" link in HPMS. If a user within an organization does not currently have access to the "plan user access" reports, organizations must submit a request to hpms_access@cms.hhs.gov.

Multi-Plan Submission Process – **Third-party Perspective** – Once consultant access has been granted to the third party by at least one contract/MCE, the third party may begin submitting multi-plan marketing materials. The following applies to multi-plan submitted materials:

- The submissions process is the same as the plan submissions process (i.e. collection of marketing content, audience, life cycle, media types, etc.), however, multi-plan submissions can only be made for Plan Created Materials
- During the initial submission process, the third party is able to select from any contracts/MCEs who have authorized access
- The third-party will select a reviewer from a list of multi-plan dedicated CMS reviewers
- Review timeframes are the same as they would be for plan submitted materials (e.g., 45-day or file and use ("F&U"))
- After the material has been approved (or accepted for F&U submissions), all plans whose contract/MCE was selected as a part of the submission will be notified (no plan notification is provided up until this point)
- Upon receipt of the email, plans whose contract/MCE was selected must "Opt-In" or "Opt-Out" of the material
- The third-party may not use the material for an associated contract/MCE unless the plan has opted-in
- HPMS sends an e-mail to the third-party for all submission updates, including when each plan provides an "Opt-In" or "Opt-Out"
- A plan opting in or out of a material does not impact the material's review status (i.e. approved or accepted)
- The third-party can add additional contracts/MCEs after the material has been approved
- The third-party will see a "tab" for each contract/MCE that is associated with the material (plans are only able to see their own "tab")

Note: Please refer to §§ 422.2262(d) and 423.2262(d) for SMID requirements for multi-plan materials.

Multi-Plan Submission Process – Plan Perspective – After the plan grants access to the marketing module for multi-plan submissions, the following happens after a material has been submitted for the plan's contract/MCE and approved (or accepted for F&U) <OR> when a plan's contract/MCE number has been added to an already approved material:

• The plan will receive an email from HPMS notifying the plan that a multi-plan material has been submitted that includes their contract/MCE number.

- Upon receipt of the email, the plan should review the material and "opt-in" or "opt-out".
 - o "Opting-In" indicates that the plan is aware of the material and is providing their concurrence that they will be associated with the submission (i.e. that the material will be used by the third-party for the contract/MCE noted)
 - "Opting-Out" indicates that the plan does not want to be associated with the submission (i.e. that the material will not be used by the third-party for the contract/MCE noted)
 - Opting-in/out does not impact the status of the material in HPMS (e.g., it will remain approved/accepted)
- Plans are responsible for the content of multi-plan materials they have opted into and responsible for ensuring the materials remain compliant with the most current requirements. See 42 CFR §§ 422.503(b)(4)(vi), 422.504(i), 423.504(b)(4)(vi), 423.505(i).

Note: The expectation is that all conversations and external reviews of the material have already occurred prior to the material being submitted into HPMS. The multi-plan submission process is not the vehicle for plan review of third-party submitted materials.

§§ 422.2261(b)(3), 423.2261(b)(3) – File and Use (F&U)

CMS designates certain marketing materials as F&U eligible based on the material's content, audience, and intended use, as they apply to potential risk to the beneficiary. A material submitted under F&U may be used five days following its submission, provided the plan certifies the material complies with all applicable standards.

- The "Marketing Lookups" function in the HPMS Marketing Module identifies what materials (for CMS Required Materials) and what media types (for Plan Created Materials) qualify for F&U submissions. Plans without an executed contract may submit F&U materials. However, once the contract is executed, CMS presumes that the plan has, by submission of the materials, attested that the material complies with all requirements regardless if the materials were submitted before or after contract execution.
- Plans may be subject to compliance actions if:
 - Materials are used before they are "accepted" (i.e. five days following the submission of the material), or
 - Materials are found during a CMS review to be out of compliance with the applicable requirements under §§422.2260 through 422.2267 and §§ 423.2260 through 423.2267.

§§ 422.2261(d), 423.2261(d) – Standards for CMS Review

- Placeholders (formerly "template materials") –CMS permits the use of placeholders to represent certain variable data in required or Plan Created Materials (except for SBs, as provided in Appendix 2). Variable data fields for premiums, cost sharing, benefits should only be used when the document is applicable for more than one plan. The type of data that will populate the placeholder dictates how the material is submitted.
 - Plans have the choice on whether to use placeholders. If a plan does not want to

use placeholders the data in the submitted materials must be bracketed (e.g., [\$10 Copay/\$15 Copay/\$20 Copay]). If the plans are using placeholders, the plan must include the data type in brackets along with a reference to where the data can be found in the spreadsheet or table (e.g. [Copay, see column "A"]). The submission for materials with placeholders consists of a zipped file which contains the material and a spreadsheet or table identifying the actual data for each variable field. Spreadsheets or tables must only include the variable data found in the submitted material for the contracts/plans associated with the submitted material.

- When using placeholders that include non-marketing content, the content can be
 represented in the material by the data type in brackets (e.g. [date], [hours of
 operation], [agent name]). In this instance, a table containing the actual data is not
 required with the submission, however, such data must be made available upon
 request.
- Remedying a previously disapproved material Plans should clearly indicate all changes/updates when resubmitting materials that were previously disapproved, such as highlighting text changes or inserting notes or identifying changes in the comments section.
- Material Replacement For the specified materials below, HPMS now has a "material replacement" functionality to allow updated materials to be resubmitted as a replacement file attachment using the same SMID. Material replacement is available for:
 - Annual Notice of Change (ANOC)
 - Summary of Benefits (SB)
 - Evidence of Coverage (EOC)
 - Star Ratings Document
 - Sales scripts and presentations
 - Enrollment scripts
 - Enrollment forms (online and paper)

If the material replacement function is used, do not mark the original material as "no longer in use."

The material replacement function is not available for previously submitted materials other than those listed above; any other materials that require changes/updates must be marked as "no longer in use" and resubmitted with a new SMID.

- **Updates to CMS Required Materials -** Plans must review all required documents for accuracy and resubmit if changes or corrections to previously submitted CMS Required Materials are identified (e.g., the benefit or cost-sharing information differs from that in the approved bid). In addition, the following requirements apply:
 - ANOC, EOC, and formulary errata must be sent in hard copy within a reasonable timeframe or electronically if the enrollee has opted into receiving electronic versions, and
 - SB addenda or reprints must be sent only to existing enrollees if the plan mass mailed the SB.