60- Day Comment Response Document

Overview of Comments

CMS received comments from Part D sponsors, PBMs, MTM vendors, and other organizations. We received over 65 comments from 17 organizations regarding revisions to the Standardized Format.

Detailed Summary of Comments

Standardized Format Section	Comment	Commenter's Recommendation	CMS Response	Revised Requirements/Documents	Revised Burden Estimates
Cover Letter	CMS received several comments regarding whether the cover letter could be modified in the case of delivery of the CMR to someone other than the beneficiary, such as authorized representative or other healthcare provider.	One commenter recommended including an option to capture when a CMR was completed with someone other than the beneficiary as is available in the current standardized format. Yet another commenter suggested the creation and distribution of a separate representative-facing cover letter again in occasions where the CMR is completed on behalf of the beneficiary, i.e. with the caregiver.	The current technical instructions explain that when the CMR is performed on the behalf of a cognitively impaired beneficiary with someone other than the beneficiary, such as the beneficiary's legally authorized representative, caregiver or prescriber, the MTM provider should discuss the delivery of summary materials with the beneficiary's representative to determine to whom and where they should be sent. CMS expects the CMR summary will be delivered to the beneficiary's authorized representative, such as the health care power of attorney, if known. When sending the CMR summary to the beneficiary's legally designated authorized representative, the inside address should include the beneficiary's name, c/o <name and address of their authorized representative>. The instructions also recommend that sponsors include an explanatory note when the CMR is performed with an authorized individual on the behalf of a cognitively impaired beneficiary. Once the revised Standardized Format document is approved by the Office of Management and Budget (OMB) through the Paperwork Reduction Act (PRA) process, CMS will release updated technical instructions. The current instructions and frequently asked questions (FAQ) documents are posted at: https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.	No	No
Cover Letter	The proposed template does not include an optional space for barcodes, document reference numbers, beneficiary identifiers, case numbers or the document title on the cover letter.	Request that CMS consider reintroducing this space in the cover letter.	Thank you for this suggestion. CMS has added the <additional space for optional plan/provider use, such as barcodes, document reference numbers, beneficiary identifiers, case numbers or title of document> to the Cover Letter.	Yes	No
Cover Letter	Commenters asked whether the hours of operation are no longer required as they were not included in the proposed standardized format.	Recommend including additional contact details, such as days and hours of operation, or the option to direct beneficiaries to call a department, rather than a specific person.	CMS added this detail to the Cover Letter.	Yes	No
Cover Letter	The proposed template appears to indicate that the plan name is no longer required.	N/A	CMS added this detail to the Cover Letter.	Yes	No
Cover Letter	Several commenters inquired whether TTY no longer required as it was not included in the proposed standardized format.	N/A	CMS added this detail to the Cover Letter.	Yes	No

Cover Letter	We received several comments regarding the removal of the plan logo from the first page of the PML and MAP.	The recommendation was to retain the logo on the first pages of each document in the standardized format for context on the beneficiary's behalf. In addition, a request was made for further instructions on the inclusion of the logo on the Cover Letter.	Based on interviews with the pharmacists and sponsor/MTM representatives, the logo was removed from the first page of the Action Plan and Medication List to save space and improve readability. It remains as an optional insert on the top left corner of the Cover Letter. More instructions will follow in the updated technical guidance.	No	No
Cover Letter	We received several comments about the contact information on the revised cover letter only including the name of a pharmacist.	Recommendations included allowing MTM provider contact information to be listed on the cover letter and on each document, similar to the current MAP and PML sections and having the flexibility of including the name and title of other authorized health care professionals, who may complete a CMR.	CMS updated the Cover Letter to allow signature of the MTM provider of the CMR, which could be the pharmacist or other qualified provider. The MTM provider information was removed from the PML and MAP in keeping with measures to reduce the length of the standardized format.	Yes	No
Cover Letter	Grammar modification: Current: Su Lista de Medicamentos le ayudará a monitorear susmedicamentos y saber cuando y como tomarlos. Your list of medications will help you monitor your medications and know when and how to take them (medications).	Recommendation: 1.Su Lista de Medicamentos le ayudará a monitorear sus medicamentos y saber cuándo y cómo tomarlos. Your list of medications will help you monitor your medications and know when and how to take them (medications).	Gracias por tu comentarios. Vamos agregar el espacio recomendado. Thank you for your comments. We will add the recommended space and accents.	Yes	No
Medication List (PML)	Agree with many proposed changes, disagreed with renaming of the Medication Action Plan (MAP) to "Recommended To-Do List". Many of the interventions/recommend ations on the MAP do not require action by the patient who receives the comprehensive medication review (CMR). This could result in patient confusion.	Consider renaming the MAP to "My Plan" as an enrollee friendly option and adding a "no action needed" or "monitor" checkbox so that the recommendation could still be documented for the patient's benefit.	The revised title for the Medication Action Plan (MAP), “Recommended To-Do List,” tested better than "Medication Action Plan" when we tested potential revisions with consumers in limited cognitive interviews in 2018. It did not cause patient confusion. The participants generally understood that the MAP included items they should complete and the revised title may have helped communicate this. In addition, participants generally liked the revised title, with several noting that it clearly indicated what the section was about. One participant explained that he was familiar with the concept of to-do lists. A few other participants suggested titles such as: “Reminders” or “Things you should know” because some of the items on the list were things that she should not do (e.g., eat grapefruit), rather than “to do” items.	No	No
Medication List (PML)	N/A	While CMS uses the term “physician,” it is noted that beneficiaries could also have a nurse practitioner or a physician assistant as their primary care provider. Accordingly, CMS should replace “physician” with “primary care providers and other specialists” to better inform the scope of providers that should receive this information.	CMS does not use the term "physician" in the proposed Standardized Format document, but rather used the term "prescriber".	No	No
Medication List (PML)	A couple of commenters sought clarification on the desired selection for the prescriber field when an over-the-counter medication is recorded.	N/A	The current technical instructions note that for non-prescribed OTCs, enter “self” or leave this field blank. The technical instructions will be updated and released after the document is approved and finalized.	No	No

Medication List (PML)	Please confirm that the "How I take it" portion of the Medication List would follow the same expectations as the "directions for use" section found in the Personal Medication List.	N/A	The "How I Take it" field notes to < Insert regimen, (e.g., 1 tablet by mouth daily), use of related devices, and supplemental instructions as appropriate >. This includes the directions for use. The current Standardized Format field is named "How I Use It".	No	No
Medication List (PML)	Some commenters pointed out the listing of either the brand or generic drug on the medication list and that inclusion of the brand when the beneficiary is on a generic medication may lead to confusion.	The recommendation was to require the name of the actual medication being dispensed as the true requirement. For example, if atorvastatin 40 mg is dispensed, the medication list must at least display "Atorvastatin 40 mg." If Lipitor 40 mg was dispensed, the medication list must display "Lipitor 40 mg." Additionally, clarification was sought that this would remain unchanged from how the PML currently functions.	We agreed with these comments and this is consistent with the current technical instructions which note: For brand drugs and branded generics, list both generic and brand names, such as "Generic Name (Brand Name)". An example is Furosemide (Lasix). For generic drugs, list the medication name as "Generic Name" (e.g., Furosemide).	No	No
Medication List (PML)	We received several comments on the "Other Information" box which allowed a pharmacist, or other provider, the space to enter general information / instruction to the patient. This field was removed in the revised standardized format but was of value for including additional patient centric information that may not have been captured elsewhere.	We recommend CMS consider re-instating the "Other Information" box. This additional section would allow CMR providers to empower the beneficiaries with valuable counseling points when needed and could be voluntarily populated at the discretion of the CMR provider.	CMS will add back the "Other Information" box to the Medication List, and note in the upcoming technical instructions that this field may be optional or deleted.	Yes	No
Medication List (PML)	We are also in support of the separation of allergies and side effects. We find that beneficiaries expressed interest in adding information to the PML on common drug interactions (39.6%), side effects (40.3%), and special instructions (40.3%). Furthermore, 34.8% requested information about alternative medications in the same class that could be cheaper."	We realize there is limited space on the PML, but guidance on specific supplemental instructions should address making the Medication List patient centered. With respect to side effects, we recommend incorporating sentinel side effects into the Medication List under its own heading and specific to each medication.	CMS does not intend to revise the content of the Standardized Format, but notes consistent with the current technical instructions and FAQ document, Part D sponsors and MTM providers are encouraged to supplement the Standardized Format with additional materials and information that may aid a beneficiary. The instructions state that the enclosure notations or postscript of the Cover Letter may be used to list or describe supplemental materials that will be included in the package with the Format. The technical instructions will be updated and released after the document is approved and finalized.	No	No
Medication List (PML)	We received comments about the allergies box being moved to the bottom of the Medication List on the proposed format.	The recommendations were to rearrange the form to include this information at the top of the form for ease of access to providers and because it is typically the first item discussed and provides background information.	Based on interviews with beneficiaries, the allergies and side effects box was separated into two boxes and moved to the end.	No	No

Medication List (PML)	Inclusion of bulleted information within the "What I should do" portion of "My To-Do List" has the potential to create undue burden in the technical development of that formatting.	This commenter recommends an approach that would allow for a non-bulleted formatting of this content.	Based on interviews with beneficiaries, participants liked the revised Action Plan, and thought the checkboxes could help patients recognize the document as a To-Do List and make it "more actionable." We received limited feedback from plans and MTM providers that the checkboxes may be difficult to program, while others did not think the checkboxes and graphics would present technical issues.	No	No
Medication List (PML)	Please specify the desired content of the "My To-Do List" when no items are identified by the CMR provider.	N/A	As noted in the current technical instructions, there may be CMRs that do not identify issues of current drug therapy or beneficiary-specific action items. The Format allows plan sponsors to enter other statements into a new MAP as appropriate for the beneficiary, such as reinforcing compliance, maintaining beneficiary's actions, and acknowledging beneficiary success in his/her medication therapy. Beneficiaries will best understand a consistent deliverable after their CMRs, including the medication action plan, even if there are no new beneficiary-specific action steps. The technical instructions will be updated and released after the document is approved and finalized.	No	No
Medication List (PML)	Grammar modification: Current: Como lo tomo | Por que lo tomo How to take them (medications) | Why I am taking them (medications).	Recommendation: Cómo lo tomo | Por qué lo tomo How to take them (medications) | Why I am taking them (medications).	Gracias por tu comentarios. Actualizamos el documento. Thank you for your comments. We updated the document.	Yes	No
Medication List (PML)	Several commenters asked about the inclusion of blank lines or rows at the end of the medication list, this would allow beneficiaries to add in medications for tracking post- CMR. If they were to be included, how many would CMS recommend?	N/A	This is a good suggestion which we will include in the updated technical instructions. We recommend the addition of a minimum of three blank rows within the completed medication list.	No	No
Medication List (PML)	Commenter supports the removal of the strength from the medication directions. However as this change is not specifically identified in the proposal, we ask for confirmation that the intent is to remove this requirement. From 1 tablet (20mg) by mouth daily to 1 tablet by mouth daily.	N/A	Thank you for your support. Yes, that was our intent. Several participants during cognitive interviews indicated that including the total dose in the "How I use it" field is confusing. Several participants noted that the strength of the medication is listed both in the medication field and the "How I use it" field. They indicated that this could be confusing when a patient is supposed to take two tablets of a particular medication – e.g., two pills that are 800 mg each, or 1600 mg total. If patients read "800 mg" on their pill bottle, then reads "1600 mg" in the "How I use it" field, the participants felt they might be confused about how much to take, which could contribute to a dangerous situation where someone is taking the wrong dose. They therefore suggested removing this information from the "How I use it" field to avoid causing confusion.	No	No
Medication List (PML)	N/A	Auto-populate the "allergies" section. The allergies section should be auto-populated with "no known drug allergies," rather than left blank, to ensure that this question is addressed during the provision of the CMR.	We agree with this comment. More information will be in the technical instructions including an explanation that the Allergies box could be deleted if there is no relevant information to include, or the MTM provider may populate the box with no known drug allergies to indicate this was discussed.	No	No

Medication List (PML)	N/A	Require information on quantity, dose, dosage form, route of administration, and frequency. This would ensure clear communication of instructions captured during the review. Inclusivity for all relevant providers.	We agree and this is consistent with the current technical instructions.	No	No
Medication List (PML)	Standardized CMR format inflexible for end user use. Options to transmit CMR via email or securely through a eMR	Increase number of medications that fit per page by patient preference. Ability to send the medication list on one page vs. multiple pages or both.	Readability is an important consideration for the Medicare Part D enrollee population. The current technical instructions document, which will be updated and released by CMS upon OMB approval of the revised Standardized Format, currently note that a 14-point font size is required except where another font size is specified in the instructions. Therefore, it may not be feasible to increase the number of medications per page on the Medication List.	No	No
Side Effects	A major concern among commenters was obtaining clarification on what information should be used to populate the side effects box and what sources, if any, were required for obtaining that information. Causes for concern were that populating with all the side effects for each drug the member was on had the potential to overwhelm the beneficiary with too much information, significantly increase the length of the document length, and increased on burden of preparing and printing such a document.	CMS should provide clarification on what is to be included in the side effects section.	The side effects field should be used to indicate the adverse drug reactions experienced by the beneficiary that are not true allergies. More information will be released in the updated technical instructions once the format is approved and finalized.	No	No
Side Effects	CMS received multiple comments on the separation of the side effects and allergies boxes in the revised standardized format and the possible confusion this may cause beneficiaries if too many were listed or if perhaps the box was left blank.	Suggestions on the side effects box included recombining with the allergy box, removing it and placing side effects beside the appropriate drug in the medication list, and moving side effects to the recommended-to-do list.	The current approved Standardized Format combined allergies or side effects in one box and instructed users to insert the beneficiary's allergies and adverse drug reactions including the medications and their effects. The technical instructions noted that if the MTM provider is able to distinguish between allergy and adverse event, the MTM provider may label true allergies with the text "allergy" after the medication. The revised Format separates these fields based on cognitive interviews conducted in 2018 with consumers and stakeholders. It was noted that using the same box for information about medications the beneficiary should and should not be taking was confusing. More information will be in the updated technical instructions, available after the standardized format is approved and finalized, including an explanation that one or both of these boxes could be deleted if there is no relevant information to include, or the MTM provider may populate the box with no known drug allergies to indicate this was discussed. In addition, if the provider identifies an action step during the review associated with an adverse reaction experienced by the beneficiary, the To-Do list would be an appropriate place to include those recommendations.	No	No

Side Effects	"Side effects to watch for" could create confusion.	Proposing changing the title to "Side effect history" or "Adverse reactions" if intention is to separate prior intolerances from allergies.	We received many comments on the separation of the allergies and side effects box from one into two and what should be included. The side effects field should be used to indicate the adverse drug reactions experienced by the beneficiary that are not true allergies. Based on comments, we will rename this field: Side Effects I Have Had. More instructions will follow in the updated technical guidance once the standardized format is approved and finalized	Yes	No
Layout	Having the first page be portrait layout and the rest landscape makes this an awkward document to staple and have the member take to their physician.	It would be better if all pages were portrait layout to make it easier for the member to use and read.	Thank you for your comment. The Medication List was revised to landscape based on interviews with beneficiaries and stakeholder feedback to decrease the length of the document. We believe that beneficiaries may detach the Medication List and take with them to appointments. Also, we recognize the technical and layout concerns raised. Therefore, we will keep the order of documents in the currently approved Standardized Format: Cover Letter (portrait), To-Do List (portrait), and Medication List (Landscape).	Yes	No
Layout	We are concerned with the change of the list to a landscape format. If the document is meant to be printed, then switching from portrait to landscape makes double sided printing more complex and requires the reader to flip and turn the document, decreasing usability. The rigidity of the Standardized Format has limited adaptability to different formats (e.g. print and electronic).	Recommend consideration be given to mandatory Standardized Format elements but not format.	See comment above. Based on the layout comments, we changed the order of the items in the document. The Standardized Format is a beneficiary-focused output, and plans must share the unaltered version with the patient by means of a printed copy or the current PDF format may also be transmitted to the patient through secure means.	Yes	No
Layout	Supportive of this format change and the printing burden should be significantly reduced as a direct result of this change.	N/A	Thank you for your support.	No	No
Action plan/Recommended To-Do List	N/A	Is there a limit of how much can be entered in the Recommended to-do list area?	CMS does not have guidance on the maximum length of the Recommended to-do list as long as pertinent information discussed during the beneficiary's CMR is included.	No	No

Action plan/Recommended To-Do List	Moving “My follow-up plan” and “Questions I want to ask” to the end of the document and removing “What I did and when I did it”. Although the MAP has been a valuable source of information, our research found about 50% of the beneficiaries do not utilize fill-in sections at all. Thus, minimizing sections with lower use may help save space, reduce beneficiaries’ burden, and improve portability.	N/A	Thank you for your comment. The "My Follow-up plan" and "Questions I want to ask" sections have been combined into a "My notes and questions" section at the end of the document. The "What I did" and "When I did it" have been combined into the "What should I do" section with added checkboxes. These changes were made based on beneficiary interviews that allowed for increased readability/accessibility, encourage engagement, and reduce burden.	No	No
Action plan/Recommended To-Do List	N/A	Suggest considering to make the column “What we talked about:” narrower to allow for more horizontal space for the “What I should do:” section. This will allow more space for the actions to be documented and will prevent the document from becoming unnecessarily lengthy.	Thank you for your suggestion. We intend to keep the columns equal width based on review of mock-ups and limited cognitive testing on the revised Format	No	
Action plan/Recommended To-Do List	One commenter requested clarification as to whether completion of the boxes in the “What should I do” section required.	N/A	Yes, the "What I should do" fields in the Action Plan should include the checkboxes and list the relevant recommendation(s), action item(s), or reinforcing statement(s) for that topic for the beneficiary.	No	No
Action plan/Recommended To-Do List	In the Supporting Statement Section A1. Need and Legal Basis, the last sentence says “Components of the CMR summary in Standardized Format should include a cover letter, personalized medication list, and action plan if applicable.” Does this mean that the action plan could be optional? Or if there is no recommended To Do, are we still expected to include a generic recommendation?	N/A	Per the technical instructions, the format includes the cover letter, the action plan and the medication list. There may be CMRs that do not identify issues of current medication therapy or beneficiary-specific action items. The Format allows plan sponsors to enter other statements into a new MAP as appropriate for the beneficiary, such as reinforcing compliance, maintaining beneficiary’s actions, and acknowledging beneficiary success in his/her medication therapy. Beneficiaries will best understand a consistent deliverable after their CMRs, including the medication action plan, even if there are no new beneficiary-specific action steps.	No	No

Action plan/Recommended To-Do List	In the 'My To-Do List' section, the proposed standardized format shows four topic boxes on the page. We request clarification on whether there is a minimum and/or maximum requirement on the number of topic boxes to include in the 'My To-Do List' section.	We ask that CMS only require a minimum of one topic box be completed, the safe disposal topic that is preset, and allow plans to add additional topic boxes beyond the four included in the template so that plans have maximum flexibility to meet the needs of their members.	Consistent with the current technical instructions, the MTM provider has flexibility to determine the most important activities to include on the Action Plan summary for the beneficiary based on the beneficiary's concerns, the therapeutic need, and the beneficiary's ability to understand and complete the recommended activities. There may be CMRs that do not identify issues of current drug therapy or beneficiary-specific action items. The Format allows plan sponsors to enter other statements into a new MAP as appropriate for the beneficiary, such as reinforcing compliance, maintaining beneficiary's actions, and acknowledging beneficiary success in his/her medication therapy. Beneficiaries will best understand a consistent deliverable after their CMRs, including the medication action plan, even if there are no new beneficiary-specific action steps. Therefore, rows may be added or deleted as appropriate.	No	No
Action plan/Recommended To-Do List	The 'What I should do:' box for each topic appears to have a requirement for each topic to include two bullet points/check boxes. However, it is unclear on whether we can insert more than two check boxes in this section. While we agree with the template as is, since it currently shows two action items, we don't want to be required to populate both for every topic as it is not always applicable or necessary	We request that CMS allow a minimum of one and a maximum of two action items per topic.	Correct, providers may populate with one or more action items for each topic even though two were shown in the Format. We will provide this clarification in the updated technical instructions.	No	No
Safe Disposal	It is very hard to include real-time drug take-back programs for each individual member's location. Researching for local take back programs will add time to the CMR documentation process and take time away from outreach to additional targeted members.	We believe a better approach would be to provide general safe disposal information so that the information can be standardized and apply to a larger population rather than include detailed locations for take back.	CMS issued a final rule (86 FR 5864), "Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Program, and Programs of All-inclusive Care for the Elderly" (CMS 4190-F2), on January 19, 2021 that implements changes to the MTM program beginning January 1, 2022. Pursuant to 42 CFR § 423.153(d)(1)(vii)(E), beginning January 1, 2022, Part D sponsors must provide to all MTM enrollees, at least annually, as part of the CMR, a TMR, or other MTM correspondence or service, information about safe disposal of prescription drugs that are controlled substances, drug take back programs, in-home disposal and cost-effective means to safely dispose of such drugs. Under 42 CFR § 423.153(d)(1)(vii)(F), such enrollees must be provided all information required at 42 CFR § 422.111(j). It was our intent to include the safe disposal information as the first item in the Medication Action Plan if safe disposal information was discussed during the CMR. However, based on this feedback, and other comments to this solicitation, the proposed document will be revised to include one My Notes & Questions" section at the end of the document, as well as the safe disposal information if discussed during the CMR, to better make use of space. CMS will include information in the updated technical instructions.	Yes	No

Safe Disposal	What I should do: <insert federal government safe disposal website information> Does CMS require the MTM provider to complete this section or, can the provider leave it blank for the beneficiary to complete?	N/A	It was our intent to include the safe disposal information as the first item in the Medication Action Plan if safe disposal information was discussed during the CMR. However, based on other comments to this solicitation, the proposed document will be revised to include one "My Notes & Questions" section at the end of the document, as well as the safe disposal information if discussed during the CMR, to better make use of space. CMS will include information in the updated technical instructions.	No	No
Safe Disposal	Understanding that this is a statutory requirement and given the number of federal government websites related to the safe disposal of prescription drugs, it is imperative for CMS to provide specifications about what information plans must provide.	Clarify which "federal government safe disposal website information" is supposed to be included in the Recommended To-Do List.	See January 2021 final rule (86 FR 5864) for the safe disposal requirements at 42 CFR § 423.153(d)(1)(vii)(E). Under 42 CFR § 423.153(d)(1)(vii)(F), such enrollees must be provided all information required at 42 CFR § 422.111(j).	No	No
Safe Disposal	We received several comments about the safe disposal topic listed on the revised format as the first recommended to-do. Concerns raised were things such as this is often not the most pressing matter for the beneficiary, it may be irrelevant to the conversation had with the MTM provider, and finally if it was a requirement.	Recommendations included may more urgent To-Do's that were raised during the CMR come before the safe disposal information; can it be a general statement rather than a To-Do; removing it from the Recommended To-Do List and instead including it on the medication list, perhaps at the bottom or in place of the side effects to watch for.	Thank you for your comment. It was our intent to include the safe disposal information as the first item in the Medication Action Plan if safe disposal information was discussed during the CMR. However, based on this feedback, and other comments to this solicitation, the proposed document will be revised to include one "My Notes & Questions" section at the end of the document, as well as the safe disposal information if discussed during the CMR, to better make use of space. CMS will include information in the updated technical instructions.	Yes	No
Safe Disposal	It is our understanding that the SUPPORT Act is requiring the mailing of safe disposal information of prescriptions that are controlled substances to all MTM program enrollees. Since not all MTM program enrollees receive a CMR, if the safe disposal information is provided in a different manner, is it still required to be included in the post-CMR standard format mailing?	N/A	No, it should only be included in the Standardized Format summary if discussed during the CMR.	No	No

Safe Disposal	It has been demonstrated that discussions about proper medication handling and disposal are generally well-received and are positively correlated with understanding the risks that come with keeping unused medications at home. Providing beneficiaries with high-quality resources on medication disposal allows them to be used later.	There needs to be explicit guidance on which federal website and/or printed information should be provided to beneficiaries.	See January final rule (86 FR 5864) for the safe disposal requirements at 42 CFR § 423.153(d)(1)(vii)(E). Under 42 CFR § 423.153(d)(1)(vii)(F), such enrollees must be provided all information required at 42 CFR § 422.111(j).	No	No
Safe Disposal	Of note, the added language in the revised version on medication disposal is sensible for beneficiaries who live at home and manage their own medications but is not relevant to skilled nursing facilities where medications are administered. We believe that MTM has the potential for high acceptance by Medicare beneficiaries in long-term care, but in order to achieve this potential, operational hurdles such as the SF need to be addressed.	N/A	See January 2021 final rule (86 FR 5864) for the safe disposal requirements at 42 CFR § 423.153(d)(1)(vii)(E). Under 42 CFR § 423.153(d)(1)(vii)(F), such enrollees must be provided all information required at 42 CFR § 422.111(j). The requirements do not distinguish between beneficiary setting; however, the information could be tailored to the individual as needed.	No	No

Safe Disposal	Commenter supports providing safe drug disposal information to MTM enrollees, with the following recommendations to ensure consistent messaging across MA-PD plans and with existing U.S. government messaging on safe disposal of drugs. Additionally, CMS has indicated that providing safe disposal information in the Comprehensive Medication Review (CMR) written summary in standardized format will not by itself meet the CMS requirement because MTM members who do not complete a CMR or decline the CMR would not receive the standardized format that would contain the safe disposal information.	To avoid plans sending incorrect or inadequate safe disposal information in the MTM standardized format written summary, commenter recommends that CMS provide template language on safe disposal in the MTM standardized format document 'My To-Do-List' section that would apply universally to all MTM members. Commenter recommends that CMS provide template language on safe disposal to include with our MTM member offer letter that would be sent to all eligible MTM members, regardless of whether or not they complete a CMR. Sending the safe disposal information at the outset of a member's enrollment eligibility would ensure that the member receives the information as early as possible.	See January 2021 final rule (86 FR 5864) for the safe disposal requirements at 42 CFR § 423.153(d)(1)(vii)(E). Under 42 CFR § 423.153(d)(1)(vii)(F), such enrollees must be provided all information required at 42 CFR § 422.111(j).	No	No
My Notes and Questions	CMS received multiple comments on the "My notes & Questions" pages included at both the end of the PML and the MAP. Questions and concerns were as follows: Could they be combined into one page at the end of the document to eliminate waste, as one page seemed sufficient? Were they only for the beneficiary or could the MTM provider populate these fields in place of the "Other Information" box?	Recommendations included removing one page entirely, clarify if this section were solely for the patient's use, re-introduce the "other information" box.	This is a good suggestion to further streamline the document and number of pages. The proposed document will be revised to include one My Notes & Questions" section at the end of the document, as well as the safe disposal information if applicable to the CMR summary, to better make use of space. CMS will add back the "Other Information" box to the Medication List, and note in the technical instructions that this field may be optional or deleted.	Yes	No

Formatting	Several commenters inquired about the new icons, fonts, and other technical guidance. Questions were raised about whether the icons were required and if so did they have to be the exact same ones, would they be provided in advance, and when could they expect detailed instructions that addressed these issues along with other technical matters.	Allow plans flexibility to determine the specific graphic icons they use to reduce implementation burden	Once the revised Standardized Format document is approved by the Office of Management and Budget (OMB) through the Paperwork Reduction Act (PRA) process, CMS will release updated technical instructions. Specifics such as font size, table borders, etc., will be laid out in the technical guidance. CMS will provide image files for the icons. Plans will be required to adhere to these guidelines as the format is standardized.	No	No
Formatting	N/A	Ability to select a font, some may need larger font some don't need a large font & want the medication list on one page, this should be based on patient preference and not predetermined .	We disagree. It is a Standardized Format. The font sizes will be specified in the technical instructions document as currently done.	No	No
Formatting	Can we expect a comment period surrounding the instructions?	N/A	Once the revised Standardized Format document is approved by the Office of Management and Budget (OMB) through the Paperwork Reduction Act (PRA) process, CMS will release updated technical instructions. There will not be a comment period on technical guidance.	No	No
Formatting	One commenter requested clarification as to whether plans required to utilize the exact same icons that are on the template.	N/A	Yes, it is a Standardized Format.	No	No
Formatting	To assist members with poor literacy in understanding the condition for which they're taking the medication (example: a symbol of a heart to remind them that the drug is for a cardiac condition), as well as the time of the day they should be taking it (example: a symbol of a sun or moon).	Allow to include symbols in the Medication List section for those members.	Updated technical instructions will be released. Symbols or text may be included in the boxes and fields.	No	No

Formatting	One commented asked that CMS include a style guide that can be utilized to generate the standardized format including, but not limited to: font type, font size, header and footer sizing and margins. This style guide should also include a template file in Word or OpenOffice format and an FAQ document, similar to that provided with the previous Standardized Format.	N/A	Updated technical instructions will be released similar to the documents previously released.	No	No
Formatting	Requests clarity on the style guide that CMS proposes be utilized to generate the standardized format including, but not limited to: font type, font size, header and footer sizing and margins. We ask that CMS provide a template file in Word or OpenOffice format to support this style guide.	N/A	Once the revised Standardized Format document is approved by the Office of Management and Budget (OMB) through the Paperwork Reduction Act (PRA) process, CMS will release updated technical instructions.	No	No
Formatting	Will CMS allow double-sided printing for the letter and the accompanying Medication and To Do Lists?	N/A	Consistent with the current technical instructions, the Standardized Format summary may be printed singled-sided or double-sided.	No	No
General	One commenter requested clarification on the page numbering in this section as page one lists “Page 2 of 2” and page two notes “Page 2 of 3.”	N/A	Thank you for pointing this out. The page numbering has been corrected in the document.	Yes	No
General	The footer on the cover letter appears incomplete “Attn: PRA Reports Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-", seems to be missing the rest of the zip code. It does not match how the Spanish version reads "21244-1850".	N/A	Thank you for pointing this out. The footer has been corrected in the document.	Yes	No

General	A CMR rate of 87% of targeted beneficiaries is a high reach estimation. Several members throughout the program year and across multiple program years have either not responded to multiple passive and active invitation attempts or are very hesitant to do anything via telephone due to fear of scams.	N/A	The CMR acceptance rate has been updated based on more recent data and is now estimated to be 71.8% in 2022.	Yes	Yes
General	Depending on how many members are determined to be "At Risk," this can affect final MTM eligibility counts and thus affect the CMR rate potentially making rates go down due to higher denominator (targeted enrollees) for the calculation. Are the star ratings cut points going to be adjusted to take this into account?	N/A	This comment is out of scope for the standardized format changes.	No	No
General	In addition, while ARBs are a very necessary population to target, they may be more resistant/hesitant to a discussion about medications and may consistently decline the discussion.	N/A	This comment is out of scope for the standardized format changes.	No	No
General	N/A	For data validation audit purposes, will CMS still refer to the new "Recommended To-Do List" as the MAP (Medication Action Plan)?	Correct, "Recommended To-Do List" is the beneficiary friendly terminology on the form and is synonymous with the Medication Action Plan.	No	No

General	Implementation of these proposed changes to the Standardized Format will require the allocation of considerable time and cost resources by plan sponsors and vendors. It is important that CMS recognize this and provide plan sponsors with details on the exact specifications and requirements of the new Standardized Format and ensure that the final specifications provide plans and vendors with sufficient time to implement them.	N/A	Yes, we recognize that these changes to the Standardized Format if finalized will require time for sponsors to implement. The technical instructions will be updated and released after the document is approved and finalized.	No	No
General	Standardized CMR format inflexible for end user use. Options to transmit CMR via email or securely through a eMR	An option to send the CMR via secure email, if the business has a platform to support it. An option to upload the CMR via secure method to an eMR, if the business has a platform to support it.	No, the Standardized Format is a beneficiary-focused output, and plans must share the unaltered version with the patient. The current PDF format may also be transmitted to the patient through secure means. CMS encourages Part D plans and MTM providers to develop a mechanism to auto-populate the Standardized Format as needed. We also permit the use of HL7 FHIR standards so the documents can be integrated into EMRs and other health information technologies (HITs).	No	No
Cover Letter	The summaries must comply with the requirements specified by CMS and thus flexibility in the presentation or delivery format of this material is limited, stifling innovative approaches that Part D plans may wish to implement in order to more clearly and efficiently communicate this information to their enrollees.	Recommended approaches that could be used by plans include more streamlined paper forms, emails, patient portals, text messaging, mobile applications (apps) and other digital, electronic technologies. Additionally, the lack of flexibility prevents enrollees from being able to specify their preferred communication method, which may limit the usefulness of this information and result in the CMR service not providing the desired results.	CMS reminds sponsors that the CMR summary in the Standardized Format may be delivered through mail or other means, including electronic means, as long as it complies with the Format.	No	No
General	The “Prepared on” date on the Medication List and To-Do List may be different from the date that the beneficiary interacted with the MTM provider (i.e. “CMR date”).	Please clarify which date belongs in the field.	This is the date the Medication List and To-Do are prepared and per the technical instructions may be different from the date the beneficiary interacted with the MTM provider. The format, FAQs and technical instructions will all be updated once the PRA package is finalized by OMB.	No	No

General	Medication List-Sources of Information: The new format does not address how to document where we received the information about the medication list. I.e.: pharmacy claims, member caregiver, prescriber.	N/A	The revisions to the PML were made for simplicity and readability, based on interviews with beneficiaries, these changes tested well and mostly appreciated. Once the format is approved and finalized, more information will be released in the updated technical instructions.	No	No
General	One commenter requested clarification from CMS as to when we can expect the final templates to be released.	N/A	The final Standardized Format documents will be released after OMB approval through the PRA process.	No	No
General	We find these revisions do not address three deficiencies of the current SF: its lack of true portability, its difficulty to use as a living document, and its inapplicability to the long-term care setting. We again strongly feel and have noted that transforming the Standardized Format into interoperable elements meaningful to beneficiaries would help address integration, portability and improve goal attainment of increased medication effectiveness and safety. We believe that an electronic version of the SF would be more convenient for patients and providers to update. In fact, were the SF permitted to exist with greater leeway, and in more of an electronic manner, providers may	N/A	CMS reminds sponsors that the CMR summary in the Standardized Format may be delivered through mail or other means, including electronic means, as long as it complies with the Format. Also, alternative formats may be used in addition to the required Standardized Format. CMS also reminds sponsors/MTM providers that the requirement to offer MTM services and CMRs to targeted beneficiaries in LTC settings is a statutory requirement.	No	No
General	The current standard form has an instructions document as well as an FAQ that provides clarification on how the form should be completed for several components. Recommend CMS provide these again to the Health Plans with the new template.	If there are no plans to provide separate documents like the ones that currently exist, recommend for CMS to make the instructions within the template more explicit to provide additional clarity to the Health Plans on expectations and intent.	Thank you for your comment, we will provide updated technical instructions with release of the final version.	No	No

General	N/A	Include the “Prepared for” and “Prepared On” identifiers in the header rather than inserting that content into the body of the document. This will create a consistent format from page to page.	Thank you for this suggestion. The formatting has been updated for consistency.	Yes	No