

**60- Day Comment Response Document****Overview of Comments**

CMS received comments from Part D sponsors, PBMs, MTM vendors, and other organizations. We received over 30 comments from 11 organizations organized into sections: Burden Estimate, General, Medication Action Plan, and Personal Medication List (PML).

**Detailed Summary of Comments**

<b>Standardized Format Section</b>	<b>Comment</b>	<b>Commenter's Recommendation</b>	<b>CMS Response</b>
Burden Estimate	CMS underestimates the costs of these reviews, their possible duplication in other settings, and cost per patient. Many plans report that the average cost of a medication review is between \$100 and 150 per patient.	Recommend CMS review the costs incurred and whether this expense is meeting the goals of the agency.	CMS reminds sponsors that the burden calculations are based on an average estimated cost to conduct CMRs across all Part D sponsors, which may vary based on the complexity of the individual case or plan sponsor or provider efficiencies. CMS also considers information reported by sponsors in their annual MTM program submission on fees established for pharmacists and other MTM providers including fees per service. Services performed in other settings outside of providing the required CMR without the provision of the Standardized Format are not factored into the burden estimate. CMS is sensitive to the burden, and will continue to monitor increases in the fee schedules reported by sponsors in the annual MTM submissions.

Burden Estimate	Current fulfillment portion does not include the cost of the envelope that in many cases is customized to meet the client branding requirements.	Factor in the cost of \$0.10 to \$0.45 per envelope.	CMS appreciates the feedback and has updated the burden calculations to incorporate a cost of \$0.02 per envelope.
Burden Estimate	The current fulfillment portion does not include the cost of handling these formats (folding and stuffing) or the costs of using a print and mail vendor.	Factor in the cost of \$0.40 per format.	CMS appreciates the feedback and has updated the burden calculations to incorporate a cost of \$0.08 per format for folding and stuffing costs.
Burden Estimate	The current fulfillment portion does not include the additional 2 pages required to handle the non-English tag lines required under Section 1557 of the ACA.	Factor in the cost of \$0.05 to \$0.07 per CMR.	CMS is still awaiting additional guidance from OCR regarding the application of Section 1557 of the ACA to the Standardized Format. Once a determination is made, CMS will take into account for future burden estimates.
Burden Estimate	The current fulfillment portion does not include translation services that may be incurred by the MTM vendor or the Sponsor in performing the CMR or translating the documents.	N/A	CMS reminds sponsors that the burden calculations are based on an average estimated cost to conduct CMRs across all Part D sponsors, which may vary based on the complexity of the individual case or plan sponsor or provider efficiencies. CMS also considers information reported by sponsors in their annual MTM program submission on fees established for pharmacists and other MTM providers including fees per service. Services performed outside of the required CMR without the provision of the Standardized Format are not factored into the burden estimate. CMS is sensitive to the burden, and will continue to monitor the fee scheduled reported by sponsors in the annual MTM submissions.

General	The form is cumbersome and not that helpful to patients.	The form should be focus tested and revised to be more meaningful.	CMS appreciates the feedback. The Standardized Format was initially developed through consumer testing and extensive stakeholder feedback. As noted in the supporting statement for this submission, from October 2014 through March 2015, we tested stakeholders' satisfaction with, and attempted to identify potential revisions to, the standardized format. The stakeholders included a diverse technical expert panel of MTM stakeholders, MTM providers and Medicare beneficiaries. These activities demonstrated that beneficiaries are satisfied with the standardized format without a consensus for any additional revisions to the standardized format. In addition, the CMS Innovation Center Enhanced MTM Model to test innovative strategies for the delivery of MTM services began January 1, 2017. We will consider lessons learned from the model and consider changes in the future based on results of this model.
---------	--	--	--

General	Form is currently only available in English and Spanish. Providing the form in additional languages would help plans comply with Section 1557 of ACA and help address health disparities. Memorializing the conversation in the language in which it was conducted is also particularly appropriate. Translating the MTM form is consistent with CMS's efforts to address health disparities. Creating a single translated model document for all plans to use is a more efficient approach than requiring each plan to develop a document separately.	Request that CMS prepare models of the form in the 15 most common languages in the U.S. and clarify whether this form is a "significant" document for purposes of Section 1557 of the ACA and thus multi-language inserts should always accompany the letter. If models cannot immediately be developed in all these languages, we ask that CMS set up a schedule to create the translated documents in a reasonable time. CMS should instruct plans to include multi-language inserts and beneficiary rights statements with MTM letters.	CMS appreciates the commenter's concerns in addressing health disparities. CMS is still awaiting additional guidance from OCR regarding the application of Section 1557 of the ACA to the Standardized Format. However, CMS continues to encourage Part D sponsors to offer and provide translations of the Format as needed to satisfy the language needs of their beneficiaries.
General	N/A	Add recommendation to update PML and MAP at every visit " <i>when there are changes</i> ".	CMS disagrees. CMS notes that the Beneficiary Cover Letter (BCL) already contains a lengthy bullet for beneficiaries to keep the PML and MAP up to date, and the PML specifically states "at every visit". MTM providers can further re-enforce this message to beneficiaries during the CMR.
General	N/A	Suggest to reverse the order of the MAP and PML.	Thank you for the suggestion. Prior testing of the Standardized Format, including testing with beneficiaries, indicated that the current order of the MAP and PML is acceptable. However, CMS will consider consumer testing the order of the MAP and PML again in the future.

General	Existing flexibility in the presentation of CMR summaries is limited to the inclusion of supplemental information only. The format with standardized information currently may not be modified which creates barriers to innovative approaches Part D plans may utilize to more efficiently and clearly communicate content to beneficiaries.	CMS should work with the pharmacy profession to modernize, test, and validate alternate formats to maximize its intended benefit for Medicare beneficiaries and to work towards implementing a new standardized format in advance of 2020.	CMS is sensitive to the commenter's desire for flexibility to provide alternative formats to the Standardized Format as required under ACA. We look forward to learning from the CMS Innovation Center Enhanced MTM model, which began on January 1st, 2017. Certain statutory and regulatory requirements are waived for model participants, so alternative formats and the effectiveness of other beneficiary communications may be tested.
General	Concerned that the current paper format does not meet the intent of the Paper Reduction Act as it averages 10+ pages and costs an average of \$1.39 to mail to the beneficiary. Believes that the current paper format is unwieldy and can be streamlined to maximize its intended benefit to beneficiaries.	Suggest changes such as removing repetitive narrative and headers from the PML and MAP to the BCL, and streamlining the messaging presented in the BCL.	CMS appreciates the feedback. As noted in the supporting statement for this submission, from October 2014 through March 2015, we tested stakeholders' satisfaction with the Standardized Format and attempted to identify potential revisions to the Format. The stakeholders included a diverse technical expert panel of MTM stakeholders, MTM providers and Medicare beneficiaries. These activities demonstrated that beneficiaries are satisfied with the Standardized Format without a consensus for specific revisions to the Format. In addition, the CMS Innovation Center Enhanced MTM Model to test innovative strategies for the delivery of MTM services began January 1, 2017. We will review lessons learned from the model and consider changes in the future based on results of this model.

General	N/A	Make format changes to the MAP and PML to minimize white space, change to landscape orientation, eliminate repetitive headers, and present in tabular (Excel-type) format.	In CMS's prior testing, beneficiaries indicated that this type of line item format was not preferred. CMS will consider further consumer testing in the future.
General	<p>Mobile app technology lends itself to addressing these gaps for those beneficiaries who desire an interactive experience where and when they need it. Utilizing mobile app technology could provide an engaging, always-on communication channel with clinicians about medications in a context that's integrated and shared across the care team to achieve the best health for beneficiaries. The most valuable asset of this alternative CMR format is the creation of two way communication channel between an MTM beneficiary and a MTM provider, a trusted clinical resource. Interactive applications that are accessible to beneficiaries duplicating the MAP and MPL functionality are currently available but are not recognized by CMS as CMRs because they do not meet current format specifications.</p>	<p>Recommends that CMS permit plans to utilize alternatives to the standardized CMR format that duplicate the CL, MAP, and MPL content requirements and provide additional choices to beneficiaries including electronic, mobile application technologies, or other innovative communication mediums.</p>	<p>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.</p>

General	Satisfaction with the standardized format should consider Puerto Rico Medicare beneficiaries, which could be different based on cultural considerations.	Consider to merge MAP and PML; it's a little overwhelming for the patients and providers to receive so much information and our objective could be lost.	In CMS's prior testing, beneficiaries indicated that this type of line item format was not preferred. We look forward to learning from CMS Innovation Center Enhanced MTM model, which began on January 1st, 2017, and will consider implementing changes based on results of this model and further consumer testing. We will consider cultural differences in the future when selecting beneficiaries and providers for testing.
General	The Standardized Format includes too much information for the patient or the caregiver and the provider. We could be more assertive if we could provide targeted information in order to achieve and comply with our goals and CMS regulations centered in patients care.	Consider the possibility to include electronic notifications based on patients' preference.	CMS reminds sponsors that alternative formats may be used in addition to the required Standardized Format.
General	In our opinion beneficiaries in LTC settings do not benefit from receiving a CMR visit because they are provided with a variety of services, both medical and personal care. CMRs conducted with these type members are often brief discussions with their nurse and therefore do not note a change in care.	N/A	CMS reminds sponsors that the requirement to offer MTM services and CMRs to targeted beneficiaries in LTC settings is a statutory requirement.

Medication Action Plan (MAP)	Recommend that the paper format be modified in the following manner to improve portability and usability for beneficiaries:	Remove the following sections: "My follow-up plan (add notes about next steps" and "Questions I want to ask (include topics about medications or therapy)".	Prior testing with beneficiaries indicated that these fields were useful. CMS will consider further consumer testing in the future.
Medication Action Plan (MAP)	N/A	Add field at bottom "Personalized message with pharmacist name/contact information if member wishes to follow up:"	CMS reminds sponsors that this field is already included at the end of the Beneficiary Cover Letter (BCL). Additional fields for the MAP would lead to an increase in the length and burden of the Format.
Medication Action Plan (MAP)	Although the purpose of the Action Plan is to provide a reminder of a course of action that the members should take to maximize the benefit they receive from the medications, the commenter, as a pharmacist finds the letters to be lengthy and confusing to beneficiaries. In this case, members may not take time to review it upon receipt in the mail.	N/A	CMS thanks the commenter for the feedback and will consider this sentiment for future consumer testing. Please note that our recent testing found that beneficiaries are satisfied with the Standardized Format without a consensus for specific revisions to the Format.
Personal Medication List (PML)	N/A	Recommended changes to the PML include: shortening instructions, combining vitamins/minerals, herbals/supplements; change "over the counter" to "over-the-counter"	Thank you for the suggestion. Prior testing of the Standardized Format, including testing with beneficiaries, indicated that the current instructions were acceptable. However, CMS will consider again consumer testing these wording changes in the future.



Personal Medication List (PML)	N/A	Recommend bolding medication names and increasing the space between medication boxes.	Thank you for the suggestion. Prior testing of the Standardized Format, including testing with beneficiaries, indicated that the current format was acceptable. However, CMS will consider again consumer testing these formatting suggestions in the future.
Personal Medication List (PML)	Consider the negative connotation of the word "using" vs "taking" in terms of therapy. "Using" may be perceived as accusatory i.e. people are typically referenced as drug "users" when it comes to issues of illegal drugs or abuse of prescriptions.	Suggest "how I take it" vs "how I use it." However, many pharmacists appreciate the word "use" because "use" better addresses topical medication application and those medications where administration may be other than oral. I would conclude that this title ("How I use it") be in an editable field where take, use, apply, administer are all choices.	CMS appreciates the feedback, and will consider testing this wording with beneficiaries in the future as well as the feasibility of implementing an editable field for MTM providers.
Personal Medication List (PML)	N/A	Suggest an additional "Carry-with" medication list attachment.	CMS conducted testing in the development of the Format and is aware that some beneficiaries would also like a single "wallet" card that lists their medications for quick reference and easy carriage. CMS considered adding a wallet card to the Format, but limited the current proposed revisions to the Format to prevent increasing the length of the CMR summary. CMS encourages plan sponsors to provide supplemental materials, such as "wallet card" lists, to beneficiaries to meet their specific needs.
Personal Medication List (PML)	N/A	For the field ("product image/identifiers" under the "<Insert other title(s) or delete this field>" ), suggest pasting an image of the medication.	CMS reminds sponsors that the Format currently provides flexibility for information product images or identifiers to be included in the PML.

Personal Medication List (PML)	The document is complex and difficult to read. The pre-formatted cells lend to a lot of empty space and can be confusing for the beneficiary. Some beneficiaries would like smaller versions that are easier to carry around and take with them to their physician visits. The current format makes it difficult to create a wallet size to accommodate beneficiary needs.	It would be easier for beneficiaries if this was in more of a strict table form and read across as a line item.	In CMS's prior testing, beneficiaries indicated that this type of line item format was not preferred. However, CMS reminds sponsors that they may provide supplemental materials, such as "wallet card" lists, to beneficiaries to meet their specific needs. CMS will continue to test enhancements to the Format in the future. In addition, the CMS Innovation Center Enhanced MTM Model to test innovative strategies for the delivery of MTM services began January 1, 2017. We will consider lessons learned from the model and consider changes in the future based on results of this model.
Personal Medication List (PML)	N/A	Consider adding a blank box for the beneficiary to put provider (doctor and pharmacy) names and contact numbers? This way in case of emergency they have all the information in one place	CMS reminds sponsors that the Format currently provides flexibility for information such as provider and pharmacy contacts to be included in the PML. However, these additions may add to the overall length of the document.

Personal Medication List (PML)	The current Format makes this a very long document for most MTM eligible members.	Propose a more simple list document in which several medications can be seen on a single page with some additional information on the back side	In CMS's prior testing, beneficiaries indicated that this type of line item format was not preferred. However, CMS reminds sponsors that they may provide supplemental materials, such as "wallet card" lists, to beneficiaries to meet their specific needs. CMS will continue to test enhancements to the Format in the future. In addition, the CMS Innovation Center Enhanced MTM Model to test innovative strategies for the delivery of MTM services began January 1, 2017. We will consider lessons learned from the model and consider changes in the future based on results of this model.
Personal Medication List (PML)	N/A	Add field at bottom "Personalized message with pharmacist name/contact information if member wishes to follow up"	CMS reminds sponsors that this field is already included at the end of the BCL. Additional fields for the MAP would lead to an increase in the length and burden of the Format.
Personal Medication List (PML)	N/A	Remove "Other information".	CMS reminds sponsors that this field is optional and may be deleted if not used.

Personal Medication List (PML)	Creating a box for every medication for Medicare patient eligible for MTM means a lot of pages due to volume of medications they take. With all of this information, how do we know the elderly patient reads it? Are we creating a better experience or more burden with all these pages? Is the goal to drive conversation about medications-that is what the Action Plan is for.	Provide the list in plain and simple language, streamlined to one page with font size appropriate for the age group, would reduce cognitive burden.	In CMS's prior testing, beneficiaries indicated that this type of line item format was not preferred. We look forward to learning from CMS Innovation Center Enhanced MTM model, which began on January 1st, 2017, and will consider implementing changes based on results of this model and further consumer testing.
Personal Medication List (PML)	N/A	Change bullet instructions to "Please use this 'my medication list' to help you keep track of all the medications you are taking. This list should include medications prescribed for you and any over-the-counter drugs, herbs and vitamins you are taking."	CMS appreciates your feedback, and will consider consumer testing this wording suggestion of 'my' versus 'personal' medication list in the future.
Personal Medication List (PML)	N/A	Change "allergies or side effects" to "My allergies or side effects from medications".	CMS appreciates the feedback, and will consider consumer testing this wording in the future.

anizations	
<b>Revised Requirements/D ocuments</b>	<b>Revised Burden Estimates</b>
No	No

No	Yes
No	Yes
No	No
No	No

No	No
----	----

No	No
No	No
No	No



No	No
No	No

No	No
No	No

No	No
No	No
No	No

No	No
No	No
No	No
No	No

No	No
No	No
No	No
No	No

No	No
No	No

No	No
No	No
No	No

No	No
No	No
No	No