

Medicare Part D Medication Therapy Management Program Improvement Project
Response to Comments Received from the 30-day Notice in the Federal Register
November 30, 2011

Notice of the proposed collection and request for comment was posted in the Federal Register, Vol. 76, No. 190 on September 30, 2011. During the 30-day comment period, three health plan organizations submitted 22 comments and/or suggestions. Eight comments are in reference to information provided in the Supporting Statement of the Office of Management and Budget (OMB) submission, five comments about the Beneficiary Cover Letter, three comments about the Medication Action Plan, and six comments about the Personal Medication List. These comments along with responses are summarized below. The comments and responses are organized into four sections: OMB Supporting Statement, Beneficiary Cover Letter, Medication Action Plan, and Personal Medication List.

I. OMB Supporting Statement

Use of Information Technology

Comment: Two commenters asked for clarification about the requirements for the use of information technology and what data elements will be captured in the Standardized Format.

Response: CMS is not collecting any of the beneficiary's data from the standardized format; see [Plan Reporting and Oversight](#) for Part D reporting requirements for medication therapy management programs. However, CMS recognizes that electronic data interchange (EDI) standards related to MTM are being developed, and that Part D MTM programs should comply with such applicable standards, as well as standards for health information technology (HIT) that intersect with the MTM program, such as standard datasets for elements that may appear on the standardized format.

Burden Estimate

Comment: One commenter disagrees with CMS' estimate that the use of the proposed Standardized Format will add an additional five minutes to the time to conduct the annual interactive CMR and complete the written document for the member. The commenter estimates that the completion of the Standardized Format in its proposed form will take approximately 30 minutes. The average time to prepare the medication action plan and summary document is approximately 15 minutes. The commenter estimates an additional 15 minutes of production time for researching the required information and populating the fields. This added research time is particularly relevant to the currently proposed "start date" and "end date" fields in the Medication List. Also, this is relevant to the need for Part D plan sponsors to provide the information language that is member-friendly and non-clinical if possible (e.g. using the term "high blood pressure" rather than "hypertension").

Response: The estimate of increased burden provided by CMS is an average. CMS acknowledges that some plans/providers will have a higher increased burden and some will have

a lower increased burden depending upon their current practices. CMS' burden estimate includes costs of programming systems to support the standardized format, which may require revisions to document templates and development of data conversion tables, such as a terminology crosswalk. CMS has also eliminated the requirement for plan sponsors to research or populate the medication start and end dates, which is described below in response to other comments (see the fifth comment in section IV below). CMS also included extra printing costs in its estimate of the burden.

Request for Clarification

1. Medication Action Plan (MAP)

Comment: One comment points out that on page 6 of the Supporting Statement, Medication Action Plan, #4 in the list, a statement is made "Created more separation between each action plan." Please specify.

Response: The statement should be interpreted as "Created more separation (space) between each action plan section." Each action plan section is comprised of 'What we talked about', 'What I need to do', and 'What I did and when I did it' text boxes.

Comment: One comment is about #5 in the list under Medication Action Plan, on page 6 of the Supporting Statement, "Another set of action item fields was added." The commenter wants clarification and wants to know if additional action item fields should be supplied beyond those items identified during CMR?

Response: Only the action item fields that are included in the MAP template should be supplied to the beneficiary; new fields for other data elements should not be added. The number of action item sections should be based on the needs of the beneficiary that were discussed during the CMR and the professional judgment of the MTM provider. CMS recommends no more than two sides of one sheet of paper for the MAP. The MAP template contains five action item sections. Blank action item sections may be deleted.

Comment: One comment asks for specification of the Font Size on the "date prepared" field that is increased as noted in the Supporting Statement page 6, Medication Action Plan, #2 in the list.

Response: The date prepared field is in 16-point font for the field title and the date.

2. Personal Medical List (PML)

Comment: One comment asks for specification of the Font Size on the "date prepared" field that is increased as noted in the Supporting Statement, page 7, Personal Medication List, #3 in the list.

Response: The date prepared field is in 16-point font for this field title and the date.

Comment: One comment asks CMS to specify how many medication sections need to be included for the beneficiary to fill in as needed (Page 7, #11 in the list).

Response: At least three blank medication sections or enough to fill the last page of the PML, whichever is greater, must be included for use by beneficiaries to update the PML as needed.

II. Beneficiary Cover Letter (BCL)

Comment: One commenter stated that the signature format is inconsistent with the first paragraph, which may be confusing to the member. The commenter suggests that either 1) generalize the signature and remove the title, e.g. replace 'MTM provider signature, name, title' with 'MTM Team' or 2) change the first paragraph to read 'Thank you for talking to us...'

Response: CMS disagrees with this comment. The first paragraph is written to conform to the health literacy guidelines. The first sentence, 'Thank you for talking with me ...' is consistent with a signature from the individual who delivered the CMR, which is preferred by beneficiaries. The signature format is to allow the MTM provider flexibility with the amount of information provided in the closing.

Comment: One commenter stated that currently failed contact letters are sent to beneficiaries where an attempt is made to contact them regarding a CMR and were unable to reach them. The commenter wants to know if this requires a standardized template and/or CMS approval.

Response: The standardized format is only required for the beneficiary cover letter, medication action plan, and personal medication list provided to a beneficiary subsequent to an interactive CMR. This standardized format is not required for other communications to beneficiaries.

Comment: One comment suggested a rewording of the second sentence of the opening paragraph, "Medicare's MTM (Medication Therapy Management) program helps you make sure that your medications are working." Commenter wants to revise the sentence to the Part D plan sponsor's name: "<insert Part D plan sponsor name>'s MTM (Medication Therapy Management) program helps you make sure that your medications are working."

Response: CMS prefers the current wording at this time. The suggested content was removed from the standardized format based upon extensive testing with stakeholders and feedback from beneficiaries. This suggestion will be considered for future revisions of the standardized format.

Comment: One comment is about the second paragraph of the BCL which reads the MAP has "steps you should take to help you get the best results from your medications." The recommended wording is: "The action plan has steps you should take to help you get the best results from your medications and stay up to date with your health and wellness needs."

Response: CMS disagrees with this comment. Addressing all of a beneficiary's health and wellness needs, though laudable, is beyond the scope of requirements for a CMR. CMS encourages Part D plans to augment the standardized format with additional materials as needed to help beneficiaries manage their health and wellness needs.

III. Medication Action Plan

Comment: Two commenters state that there may be cases where there is no actionable item. One commenter stated that a new MAP is not necessary for the MTM participant other than to reinforce current behaviors and proposed using a standardized statement reinforcing compliance. The other commenter suggested that the requirement to include a MAP is inconsistent with proposed revisions to the MTM Program Federal Regulation, Federal Register 76: 196, page 63086, which states that a comprehensive medication review "may result in the creation of a recommended medication action plan ..." (emphasis added by commenter). This commenter

asked how the standardized format may be revised if a CMR does not result in a recommended medication action plan.

Response: The standardized 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 their medication therapy. CMS recognizes that, although there may be no action items from a given CMR, beneficiaries will best understand a consistent deliverable after their CMRs, including the beneficiary cover letter, medication action plan – even if there are no new beneficiary-specific action steps, and personal medication list. Requiring the beneficiary to refer to a previous MAP may be confusing to beneficiaries and affect their ability to comply with current recommendations for their medication therapy.

Comment: One comment suggested consolidating the boxes "What we talked about" and "What I need to do" into one box "What we talked about and what I need to do."

Response: Health literacy guidelines suggest that separating this type of material in simple categories makes it more easily readable and reduces the overall burden on the end user in comprehending the material. Testing with beneficiaries also indicated a preference for the current format. Therefore, CMS supports two distinct boxes for these items.

Comment: One comment recommends that the MAP should be formatted with one row for each item, instead of stacked columns.

Response: Health literacy guidelines suggest that separating this type of information into simple categories makes it more easily readable and reduces the overall burden on the end user in comprehending the material. The 'What I need to do' field is immediately followed in the same row by the 'What I did and when I did it field' to link recommendations to actions and to simplify the recording of beneficiary's notes. Testing with beneficiaries also indicated a preference for the current format.

IV. Personal Medication List

Comment: One comment suggested adding "nutritional supplements" to the list of items in the check list box.

Response: Nutritional supplements may be added to the list as changes are considered for future revisions of the standardized format.

Comment: One comment states that there is no field to capture the filling pharmacy information, including the phone number, and suggested that an additional box should be added to record the filling pharmacy information.

Response: CMS disagrees with this comment. The beneficiary's primary pharmacy may be listed in the "Other Information" field. Pharmacy information may also be added to the "Insert other titles" field; this field allows the Part D plan to define its title and content to capture other medication-related information that plans/providers prefer to include in a medication list.

Comment: One comment is about the statement "Share this with your family or caregivers too." The commenter stated that the statement may be upsetting to those who live independently and

that this statement should be deleted. Not all Medicare members live with family members or have caregivers.

Response: This statement was added based upon input from beneficiaries and other stakeholders. CMS will continue to monitor and document feedback on this issue as the standardized format is revised in the future.

Comment: The proposed draft of the PML discusses each medication a member is taking separately from the others. Rather, it would be easier for members to use/read the PML if formatted with a row for each medication with respective columns for the required information. Each row would contain an individual medication as displayed in the example.

Response: The present format is based upon the health literacy guidelines and input from beneficiaries and other stakeholders. In addition, a single-row, columnar format does not accommodate the required number of fields with 14-point font.

Comment: One comment suggested deletion of the start/stop dates from the PML because such information is very difficult to determine.

Response: In testing, beneficiaries and other stakeholders indicated these fields were useful. Since the PML should only include current medications, the date stopped field is not intended to be completed by the MTM provider. The instructions for the PML have been revised to indicate that the start and stop dates are for beneficiaries to complete, and that the plan sponsor may enter estimated dates if known or based upon beneficiary-reported data, or leave blank for the beneficiary to enter. This will be clarified further in the guidelines for use of the standardized format.

Comment: The instructions for the PML state that the list should be kept up-to-date with respect to prescription medications, over-the-counter drugs, etc. It is not clear from the instructions as to what party is responsible for completing the information related to the non-prescription items. The commenter requests clarification as to whether the Part D plan sponsor is responsible for providing this information or the member is to provide this information. The instructions should indicate such responsibility.

Response: A CMR is a review of a beneficiary's medications, including prescription, over-the-counter (OTC) medications, herbal therapies and dietary supplements, that is intended to aid in assessing medication therapy and optimizing patient outcomes. The use of over-the-counter medications is important for drug utilization review, and should be captured during the interactive CMR and reported in the PML by the Part D plan sponsor when the PML is initially generated. This will be clarified further in the guidelines on using the PML.