

MEDICARE PART D MEDICATION THERAPY MANAGEMENT (MTM) PROGRAM STANDARDIZED FORMAT

Frequently Asked Questions (FAQs)

(Revised August 15, 2012)

GENERAL QUESTIONS (New or revised: #18 and 20)

1. **Question: Must an annual comprehensive medication review be conducted in a face-to-face interactive setting?**

Answer: No, sponsors are required to offer an annual comprehensive medication review (CMR) for targeted beneficiaries with written summaries in CMS' Standardized Format, which must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider. Therefore, while the CMR may be conducted via face-to-face, other methods of delivering the CMR in real-time, such as phone or telehealth consultations, would satisfy the requirements.

2. **Question: How soon does a beneficiary need to be given the summary documents following a CMR?**

Answer: Plans may provide the Standardized Format materials to a beneficiary immediately following a CMR, or if distributed separately, materials must be sent out within 14 calendar days.

3. **Question: Must the MTM Program Standardized Format be completed and sent to the beneficiary each time a targeted medication review (TMR) is performed?**

Answer: No, the Standardized Format is required after a CMR and is not required for TMRs.

4. **Question: Is the MTM provider required to send a copy of the beneficiary's MTM Program Standardized Format to his/her prescriber?**

Answer: No, it is at the discretion of the beneficiary and/or professional judgment of the MTM provider or Part D plan to provide a copy to targeted prescribers in order to coordinate beneficiary care.

5. **Question: Will changes to the MTM Program Standardized Format be allowed in order to make the document more compatible with plan-specific electronic medical records (EMRs)?**

Answer: No, the Standardized Format is a beneficiary-focused output, and CMS encourages Part D plans and MTM providers to develop the crosswalks and data set transmissions needed to auto-populate the Standardized Format to make it compatible with current EMRs and other health information technologies (HITs). CMS will consider changes to the Standardized Format in the future.

6. **Question: Will CMS collect and approve MTM programs' versions of the Standardized Format documents (i.e., beneficiary cover letter, medication action plan, and personal medication list)?**

Answer: No, CMS will not require MTM programs to submit their Standardized Format documents for approval by CMS. The Standardized Format documents are not marketing material and should not include any marketing messages, marketing disclaimers, or other promotional material. However, plans should know that CMS can request a copy of these documents at any time.

7. **Question: Will CMS review and approve alternate formats and content for the beneficiary cover letter, medication action plan, or personal medication list?**

Answer: No, CMS will not consider alternate formats or content at this time. Part D plans are encouraged to supplement the Standardized Format with additional materials and information that may aid a beneficiary. CMS will consider changes to the Standardized Format in the future.

8. **Question: Part D plans may contract with a pharmacy benefit manager (PBM) to provide MTM services, and the PBM may further subcontract with another entity to perform some or all MTM services. For the < MTM PROVIDER HEADER > sections, should the information for the PBM or the MTM subcontractor be listed?**

Answer: During testing, beneficiaries indicated a preference for the MTM provider's contact information. Therefore, CMS recommends that the < *MTM PROVIDER HEADER* > sections should include the contact information of the individual who conducted the CMR, unless precluded by MTM program structure or procedures.

9. **Question: Can Part D plans change the layout of the Standardized Format as long as the required content is included, such as using a landscape orientation or one row for each item rather than stacked columns?**

Answer: No, the current layout of the Standardized Format is designed to make the documents more accessible to Medicare beneficiaries. During consumer testing, beneficiaries preferred the portrait layout and the structure of the tables.

- 10. Question: The instructions for the Standardized Format state that text sections and field entries must be printed with a serif font, and a sans serif font may be used for the headings and titles printed in bold font. However, we do not see this difference in the font in the samples provided in Appendix B of the instructions. Which headings/titles in the Standardized Format should be in a bold, sans serif font?**

Answer: A sans serif font, such as Arial or Calibri, may be used in headings and titles within the Standardized Format; this is optional but not a requirement. In the samples presented in Appendix B, CMS chose to use a serif font, Times New Roman, for text sections as well as all titles and headings.

- 11. Question: May we determine the position of the logos in the header or should they remain in the positions as presented in the Standardized Format?**

Answer: The MTM provider's information should appear on the left side of the header, and the plan's logo should appear on the right side of the header on the first page of each form, generally as indicated in the Standardized Format. We did not specify exact locations and size limits due to the differences in content of MTM provider information and variable sizes of plan logos. In the completed sample, we chose to include the MTM provider information and plan logo in the header section of the documents, which is above the top 1-inch document margin. The MTM provider information and plan logo could be located lower on the page or could exceed the top margin within the header due to the number of lines needed or logo size, thereby pushing content downward. We also provided blank space on the right side of the cover letter that may be used for larger plan logos.

- 12. Question: The paper size is 8.5" x 11", and a 1-inch margin is required on all sides, which leaves 6.5 inches for print space. However, the charts for the Medication Action Plan and the Personal Medication List are 6.62 inches wide, which does not leave a 1-inch margin on both sides. Is this an oversight or is there a range of allowable widths?**

Answer: CMS used Microsoft Word 2007 to create the Standardized Format documents with 1-inch document margins, and inserted a default table for the Medication Action Plan and the Personal Medication List. Although the software inserts a default table structure that is slightly larger than the side margins, the content of the tables when prepared satisfies the 1-inch document margin. This is not an oversight, but may be a consequence of our choice of software. In recognition of this discrepancy, and to provide additional flexibility for implementation of the Standardized Format, we revised the following specifications:

- (1) *Margins:* 0.9 to 1 inch on all sides.
- (2) Full-width table fields in the MAP and PML (e.g., What we talked about, Medication, respectively): width is 6.5 to 6.7 inches.
- (3) Half-width table fields in the MAP and PML (e.g., What I need to do, Why I use it, respectively): width is 3.25 to 3.35 inches.

13. Question: Is it acceptable to modify the footers, such as to include taglines, disclaimers, the Federal Contracting Statement and other plan information?

Answer: No, the footers must only contain the information specified by CMS as described in the detailed instructions document. There is limited variability in the Standardized Format for Part D plans to include additional information. The documents are not marketing material and should not include any marketing messages, marketing disclaimers, or other promotional material.

14. Question: In the instructions for the 2013 Standardized Format, it states that the required font for the CMS form number and OMB approval number in the footer and the Paperwork Reduction Act (PRA) statement is “Helvetica, 7-point.” Can plan sponsors use a font that is comparable to Helvetica? Helvetica is not a standard Microsoft Office font and is not available in all printers.

Answer: Yes, the instructions on page 3 are revised to state: Where a specific font is specified, the plan sponsor may choose an alternative, equivalent font with the same size, space, and serif specifications and appearance (e.g., 7-pt Arial substituted for 7-pt Helvetica). The instructions for the footer and PRA statement on page 4 are also revised to allow an equivalent font to be used.

15. Question: Can we include a barcode at the bottom of all pages of the Standardized Format to allow our print vendor to utilize bar coding to ensure that members get the correct letter contents?

Answer: The barcode could be placed in the margin, so that it does not interfere with the required content and position of Standardized Format material (i.e., the required footer).

16. Question: What does CMS require if a beneficiary resides in a Long-Term Care facility?

Answer: CMS Final Rule (4157-FC) revises 42 CFR § 423.153(d), and sponsors must offer a CMR to all beneficiaries enrolled in the MTM program at least annually, including beneficiaries in long-term care (LTC) settings. In the event the beneficiary is cognitively impaired and cannot make decisions regarding his or her medical needs, we recommend that the pharmacist or qualified provider reach out to the beneficiary's prescriber, caregiver, or other authorized individual, such as the resident's health care proxy or legal guardian, to take part in the beneficiary's CMR. A written summary in CMS'

Standardized Format must be provided following each CMR, whether the CMR is provided to the beneficiary, or to the authorized individual who may take part in the CMR if the beneficiary cannot participate.

17. Question: If a consultant pharmacist performs the CMR in a long-term care setting, does information about the consultant pharmacist have to be indicated anywhere on the Standardized Format? Could we put both the plan's and the consultant pharmacist's contact information, including email addresses and/or telephone numbers, on the CMR summary?

Answer: During testing of the Standardized Format, beneficiaries indicated a preference for the MTM provider's contact information to be included in the documents. Therefore, CMS recommends that the contact information of the individual (i.e., consultant pharmacist in this case) who conducted the CMR should be included in the following sections, unless precluded by MTM program structure or procedures:

- MTM Provider Header
- Paragraphs in the Cover Letter, Medication Action Plan, and Personal Medication List describing who to contact with questions
- Closing of the Cover Letter (i.e., MTM provider signature, name and title)

Due to the variations in structure and administration of Part D plans and their MTM programs, CMS is recommending but not dictating the specific content for the contact information to be used in the Standardized Format. The instructions for the Standardized Format allow flexibility for the plan sponsor to insert contact information that will be most useful for beneficiaries to get prompt answers to their MTM-related questions by contacting appropriate MTM program representatives and/or providers as easily as possible. For example, as you suggested, a plan sponsor could include more than one point of contact as well as multiple contact methods, including telephone numbers and/or email, as appropriate.

18. Question: In the event the beneficiary is cognitively impaired and the CMR is performed with an authorized individual on the beneficiary's behalf, how can the Standardized Format be changed to reflect this and to whom should the summary be delivered?

Answer: Part D plans are required to offer a CMR to all eligible beneficiaries, regardless of setting. In the event the beneficiary is cognitively impaired and cannot make decisions regarding his or her medical needs, we recommend that the MTM provider reach out to the beneficiary's prescriber, caregiver, or other authorized individual, such as the beneficiary's health care proxy or legal guardian, to take part in the CMR.

When the CMR is performed with an authorized individual on the beneficiary's behalf, during the CMR, 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 preparing the summary for the cognitively impaired beneficiary, we recommend the following changes to the Standardized Format:

1. Include an explanatory note in the Additional Space section near the top right of the Cover Letter, such as the following:

NOTE: A review of your medications was done on <i><date of CMR></i> with <i><name of beneficiary's representative></i> who served on your behalf. Here is a summary of your medication review.
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2. The address of the Cover Letter will be revised to the beneficiary, *c/o <name and address of their authorized representative>*.
3. If someone other than the beneficiary's authorized representative participated in the CMR as the beneficiary's proxy, then the participant's name should be included as a data source where indicated in the first paragraph of the PML. In this case, the summary may also be Cc:d to the beneficiary's proxy who participated in the CMR, if appropriate for treatment purposes.

CMS will evaluate additional changes to the Standardized Format based on experience beginning in 2013 and consultation with stakeholders.

19. Question: The Spanish version of the Standardized Format states to list dates as “mes/día/año” meaning month/day/year. Spanish dates should be listed as “día/mes/año” as this language states the date as day/month/year. Please provide clarification to all plans regarding how the Spanish date should be listed.

Answer: We follow the English format for Spanish translations of the date because the document will be used within the United States. Different conventions exist around the world for date and time representation, both written and spoken. However, people from foreign countries living in the U.S. have adopted and understand the national standard format (month/day/year). This format is also consistent with translations from other federal agencies, including the Social Security Administration and the Internal Revenue Service.

20. Question: We suggest changes to certain phrases in the Spanish translation of the Standardized Format. For example, in the Medication Action Plan, change the phrase

“escriba los pasos próximos” to “anote los próximos pasos.” In the Personal Medication List, replace the phrase “Otra Información” with “Información Adicional.”

Answer: We appreciate these suggestions but decline to make them. The Medicare program attempts to consistently use terms and phrases, in Spanish as well as in English, with the widest acceptability across all locales that we serve. We acknowledge that there may be different linguistic or style preferences for any translation, and have chosen the current translation as a reasonable compromise for use in the Part D program.

21. Question: Where can I find more detailed information and field specifications for the Standardized Format?

Answer: Detailed instructions are available on the CMS website at:
<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html>.

COVER LETTER (CL) (New or revised: none)

1. Question: Can the < Insert date > date field be right justified?

Answer: No, the < *Insert date* > date field may not be moved. CMS will consider this option for future changes to the Standardized Format.

2. Question: Should we apply the exact same text breaks as shown in the example Cover Letter (CL)?

Answer: It is not necessary or expected that you match the example CL and break the text in exactly the same spaces. The content of the cover letter will vary by beneficiary and plan, and you may also choose a different font type than our template, as described in the instructions, which may affect the break points.

3. Question: The address lines on the CL for both the provider and patient are limited to 3 lines in the example, which allows it to fit on one page. Many patients or providers have 4 or more lines (some up to 6 – especially in nursing homes) in their address. Do you have a recommendation of how to limit the CL to one page?

Answer: The instructions indicate that the CL may require both sides of one sheet of paper. The completed sample CL is only an example of how the documents could look based upon fictitious information. Each plan must customize the Standardized Format based on the structure of the plan’s MTM program and the needs of the beneficiary.

4. **Question: Some printers cannot print on both sides of one sheet of paper. In such circumstances, can we print the CL on two sheets of paper?**

Answer: Yes, we are revising the instructions to state that the length of the CL is limited to one piece of paper if printed double-sided, or two pieces of paper if printed singled sided.

5. **Question: Within the body of the CL, is the telephone number sufficient, or are providers required to include the “days/times, TTY, etc.”?**

Answer: Beneficiaries found that including the days and times of availability of the MTM provider (e.g., Monday through Friday, 9 a.m. to 5 p.m.) was helpful. This contact information should be included in addition to the telephone number. CMS also encourages Part D plans to include information that will be relevant to their beneficiaries, such as availability of text telephones and language translation services. The postscript of the CL may be used to describe the availability of the materials by alternative methods, such as text telephones, Braille, or alternative languages, and the availability of language translation services.

6. **Question: Can the MTM sponsor outline additional information that will be part of the package (e.g., educational handouts) in the CL?**

Answer: The body of the CL may not be changed to include additional information that will be part of the package. The enclosure notations or postscript of the CL may be used to describe other materials that will be included in the package to supplement the Standardized Format to help beneficiaries manage their healthcare needs. Marketing or other promotional materials should be not included with the Standardized Format.

7. **Question: Should the signature on the CL use a cursive font or an actual graphic of the signature? Is there a size limit specification for the signature graphic especially the number of lines allowed for it?**

Answer: The CL should be signed with a cursive signature, if possible, of the individual who performed the interactive CMR with the beneficiary, with printed annotation of the name in order to be understood. Although the actual signature on the letter is preferred, CMS understands that this may not be possible given the structure and procedures of some Part D MTM programs, and is allowing flexibility for the Part D plan to select the source of the signature, such as the handwritten signature, graphic of the signature, or font of the signature. CMS did not identify a specific size or font limitation for the signature, so a 14-point font is required for a printed signature as described in the General Formatting Specifications, and a cursive font is recommended if a printed name is used in lieu of the signature.

MEDICATION ACTION PLAN (MAP) (New or revised: none)

- 1. Question: If a beneficiary has had no medical changes since his/her last MTM encounter, is the provider required to distribute a Medication Action Plan and/or Personal Medication List (MAP/PML)?**

Answer: Yes, a new completed Standardized Format must be provided to all beneficiaries following the annual comprehensive medication review (CMR). All parts of the Standardized Format must be updated; language stating "See previous MAP/PML" is not acceptable. 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. Other statements may be entered 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.

- 2. Question: Can MTM programs use a catalog of standard statements for the content of the MAP and PML?**

Answer: CMS does not prohibit the use of a catalog of standard statements, and understands that such catalogs will develop over time. However, the content of the documents must be tailored to the specific needs of the beneficiary. Any catalog of standard statements should also allow the MTM provider to further customize the information to the specific needs of the beneficiary. CMS encourages Part D plan sponsors to develop crosswalks to convert clinical information into beneficiary-friendly language (e.g., using the term "high blood pressure" rather than "hypertension").

- 3. Question: Can a free-text, additional information section be added to the MAP, such as to emphasize education discussed during the CMR that may not fit into one of the other sections?**

Answer: No, a free-text, additional information field may not be added to the MAP. The height of rows within the action item fields may be increased to accommodate the information to be shared with the beneficiary. Part D plans are encouraged to supplement the Standardized Format with additional materials and information that may aid a beneficiary.

PERSONAL MEDICATION LIST (PML) (New or revised: #12)

- 1. Question: Double-sided print was noted as allowed for the CL and MAP, but was not mentioned for the PML. Can we also use double-sided print for the PML using the appropriately weighted paper?**

Answer: Yes, the PML may be printed either single or double-sided.

- 2. Question: How far back does the MTM provider need to review claims data to get an accurate picture of current and historical medication use?**

Answer: CMS suggests a minimum look back of 6 months to identify current medications and prescribers, and for utilization review. The PML is meant to capture medications currently in use at the time of the CMR.

- 3. Question: A medication may be available as a generic, branded generic or brand product. How should the name of the medication be listed within the PML?**

Answer: The name of the medication should appear in a consistent format as: “Generic Name (Brand Name if applicable).” For brand drugs and branded generics, list both generic and brand names, such as “Generic Name (Brand Name).” A brand drug example is: Furosemide (Lasix). A branded generic example is: Amoxicillin (Trimox). For generic drugs, list the medication name as “Generic Name” (e.g., Furosemide). In other words, for generic medications where the product name is the generic name, the printed medication name should only appear once.

- 4. Question: Our PBM has information regarding what medications were dispensed to members. In the “Medication” field, can the dispensed medication information be included? The brand/generic distinction may be confusing to some members.**

Answer: The description of the product dispensed in the Medication field of the Personal Medication List must comply with the instructions for the Standardized Format, with the generic name first and, if applicable, followed by the brand name in parentheses, product strength and dosage form.

- 5. Question: It is important to share with the beneficiary clear instructions on how to use the medications correctly. How should the instructions be written for oral medications that are solid or liquid dosage forms? What about non-oral dosage forms (e.g., injections, topicals, inhalations)?**

Answer: For the oral dose that the beneficiary takes, it should, when appropriate and reasonable, include both the number of tablets/ capsules/ teaspoonfuls, etc. and the strength (e.g., 3 teaspoonfuls (27mg) by mouth every 8 hours).

For topical dosage forms, such as gels, creams, lotions, ointments, and drops, the dose strength does not need to be included in the directions (e.g., apply to affected area every 12 hours).

For other non-oral dosage forms, such as injections, nasal and oral sprays, as well as transdermal patches, should include the strength of medication in a dose (e.g., apply 1 patch (5%) every 12 hours).

- 6. Question: Pharmacy claims data does not currently include the purpose for the medication and the directions for the beneficiary to use the medication. If this information is completed from beneficiary-reported data, may we add a disclaimer stating that this is patient-reported data and not from prescription claims data?**

Answer: MTM providers may use several strategies to acquire the required information. The forms should not be created using claims data alone, but include information gathered and clarified during the interactive CMR. It should be expected that some required information will come from the beneficiary, and it will be up to the discretion of the MTM provider to contact prescribers for verification of information that appears incorrect or unreasonable (this may affect content of the MAP) based upon MTM program protocols. The sources of information for the PML will be clearly stated in the first paragraph of the PML, so a disclaimer is not necessary.

- 7. Question: For the “How I use it” and “Why I use it” fields, is it allowable to leave this field blank in cases where the member does not recall how or why the medication is being taken?**

Answer: The PML is a reconciled list of all the medications in use (i.e., active medications) by the beneficiary at the time of a CMR. Information for this section may be pre-populated by the Part D plan and must be completed and updated with information provided by the beneficiary and/or caregiver during the consultation. Part D plans must also collect and report the purpose and instructions for the beneficiary’s use of his/her medications.

MTM providers may use several strategies to acquire the required information. The forms should not be created using claims data alone, but include information gathered and clarified during the interactive CMR. It should be expected that some required information will come from the beneficiary, and it will be up to the discretion of the MTM provider to contact prescribers for verification of information that appears incorrect or unreasonable (this may affect content of the MAP) based upon MTM program protocols.

It is not acceptable to leave these fields blank. The instructions and purpose for using the medication is necessary for a comprehensive review of the beneficiary’s drug therapy to optimize patient outcomes, by helping beneficiaries understand their medications and how they relate to their treatment plans; engaging beneficiaries in the management of their drug therapy; and improving both communication about medications and tracking of all medications, including self-prescribed medicines, with their healthcare providers.

8. Question: How can the medications on the PML be cross-referenced to recommendations on the MAP?

Answer: CMS considered approaches to cross-referencing the PML and MAP in the course of development and testing with beneficiaries and stakeholders. However, there was no consensus solution that met the need to make the forms easy to understand for beneficiaries. The MTM provider has the discretion to choose how to make reference to the medications on the MAP in the “What we talked about” field, such as to list the medication first or add emphasis to that specific text. On the PML, the optional “insert other titles...” field could be used for a note such as “see medication action plan” if applicable.

9. Question: In the optional “<insert other titles or delete this field>” field, is it allowable to provide First Databank supplied images, even though such images may not be identical to the Member’s medication?

Answer: This optional field is intended to capture other medication-related information that Part D plans and MTM providers prefer to include consistently in a medication list, such as images of medication. However, it would not be acceptable to include incorrect information, such as images that do not match the beneficiary’s actual medication.

10. Question: What if the beneficiary does not know the start date of a particular medication and claims data are unable to provide an accurate date?

Answer: The instructions for the PML indicate that the start and stop dates are for beneficiaries to complete. The MTM provider or Part D plan may choose to enter the estimated start date if known or base the start date on beneficiary-reported data. MTM providers may leave the start date field blank.

11. Question: Can the “Other Information” field be segmented into sections to account for each category of information included?

Answer: Yes, information in this field could be separated in various ways at the discretion of the provider, in keeping with general formatting requirements of the Standardized Format and to satisfy the needs of the beneficiary.

12. Question: Will CMS create a blank PML for Plans to post to their website?

Answer: CMS is not planning to develop a blank PML for plans to post on their websites. CMS recommends that Part D sponsors develop a blank Personal Medication List (PML) for beneficiaries to complete themselves, and post it on their website. Although a PML for self-completion is not subject to the requirements of the Standardized Format for the CMR summary, CMS suggests that the blank PML should be

based upon the sponsor's customized version of the CMR Standardized Format, which may include the plan's logo, specific fonts, etc. CMS also suggests the following changes to create a blank PML for self-completion based on the Standardized Format PML:

1. Delete the italicized instructions that are included in many fields.
2. Increase the height of the **Allergies or side effects** field, especially if additional instructions will be imbedded in that field.
3. Replace the first paragraph with the following text in 14 point font:
This medication list may help you keep track of your medications and how to use them the right way.
4. Change the title of the *< Insert other title(s) or delete this field >*: to **Notes:** so the beneficiary may enter more information for each medication.
5. Increase the height of the **Other information** field, especially if additional instructions will be imbedded in that field.
6. Replace the last paragraph with the following text in 14 point font:
If you have any questions about your medication list, call your physician, pharmacist, or medication therapy management provider.
Alternatively, Part D sponsors may direct inquiries to their applicable beneficiary support center.
7. Delete the Paperwork Reduction Act Statement and CMS required footers containing the CMS form number and OMB approval number.

The revisions described above for a blank PML for self-completion do not apply to the summary documents given to a beneficiary after a CMR. An individualized, written summary in CMS' Standardized Format must be provided to the beneficiary or their authorized representative following each CMR.