

**MEDICARE PART D
MEDICATION THERAPY MANAGEMENT PROGRAM
STANDARDIZED FORMAT**

Frequently Asked Questions (FAQs)

GENERAL QUESTIONS

- 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: 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.

11. 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.

12. 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

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: Within the body of the cover letter (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.

MEDICATION ACTION PLAN

- 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

- 1. 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.

- 2. 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: 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). This would ensure a consistent format of: "Generic Name (Brand Name if applicable)."

- 3. 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).

- 4. 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.

- 5. 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.

- 6. 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.

(Revised April 9, 2012)