Medicare Part D Medication Therapy Management Program Improvements – Standardized Format

Response to Comments Received from the 60-day Notice in the Federal Register

Notice of the proposed collection and request for comment was posted in the Federal Register, Vol. 76, No. 104, on May 31, 2011. During the 60-day comment period, 26 organizations submitted 234 comments. Nineteen comments were from Medication Therapy Management (MTM) vendors, 31 were from advocacy groups, 108 were from associations, and 76 were from health plans. There were 6 comments about comprehensive medication reviews, 34 general comments about the standardized format, 40 comments about the Beneficiary Cover Letter, 46 comments about the Medication Action Plan, and 108 comments about the Personal Medication List.

CMS has engaged stakeholders throughout the development of the standardized format, and appreciates their comments, suggestions, and questions in response to the request for comments. CMS' responses are given below, organized into four sections of the standardized format (Format): Global Recommendations, Beneficiary Cover Letter (BCL), Medication Action Plan (MAP), and Personal Medication List (PML). Within these sections, comments and responses are further divided into relevant subsections.

I. Global Recommendations

Support for the Standardized Format

Comment: Several commenters expressed support for the changes CMS has made to the standardized format, including ease of navigation and understanding, the benefit to beneficiaries, the value of implementing a standard format, support for the vertical or portrait format, and appreciation for CMS' consultation with stakeholders.

Response: CMS appreciates all the comments that support the standardized format and its value to beneficiaries and MTM programs, and all the suggestions submitted by stakeholders.

Literacy Level

Comment: Several commenters noted that the readability and literacy level of the format should be evaluated and user tested because it exceeds the reading and literacy level of many Medicare beneficiaries. Some commenters suggested revisions to the 5th or 6th grade level, compliance with the Plain Writing Act of 2010, and an appropriate level for medical foreign language interpretative services.

Response: CMS appreciates the concerns about the ability of beneficiaries to understand the standardized format, and has tested and revised it to improve the literacy level and readability of the documents while maintaining consistency with delivery of the required content.

Language

Comment: Two commenters requested that CMS provide the format in languages other than English so that it can be supplied to beneficiaries upon request. One commenter stated that in calendar year 2012, CMS requires plan sponsors operating in areas where the 5-percent language requirement threshold is met to provide non-English materials upon beneficiary request.

Response: Although MTM materials are not subject to translation requirements, CMS encourages Part D Plans to provide translations of the format as needed to satisfy the language needs of their beneficiaries. CMS will consider providing a Spanish version of the standardized format prior to the January 2013 implementation date.

User Testing

Comment: Two comments suggested conducting user testing on the format. User testing of the format populated with realistic data would help identify any problem areas that may need improvement. Another commenter indicated that standards for user testing have not been described.

Response: The standardized format populated with realistic data was tested with beneficiaries using focus groups and one-on-one interviews. A contractor conducted user testing using several methods and populations, including interviews and focus groups with beneficiaries, consultation with a panel of experts, and surveys with MTM providers, prescribers, and plan sponsors.

Program Implementation

Comment: A few commenters expressed concern that the format assumes a personal communication occurred between the MTM provider and the beneficiary. Residences in LTC facilities and some members are simply unable (or unwilling) to participate in an interactive CMR despite several attempts, and some members are unresponsive or decline the interactive portion of the CMR, so the documents should include altered language to account for cases where there is no direct contact. The commenters asked for clarification on whether CMS expects plans/providers to send a written summary of the CMR to a member who declines interaction but does not opt out of the program. The commenters asked if the format is required only for patients that participate in an MTM service with a pharmacist.

Response: As described in the CMS Final Rule (4144-F), the standardized format applies to interactive CMRs that Part D MTM programs must offer to eligible beneficiaries. The CMS Final Rule amends 42 CFR § 423.153, paragraphs (d)(1)(vii)(B) and (d)(1)(vii)(D), as follows:

> (B) Annual comprehensive medication review with written summaries. The comprehensive medication review must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider unless the beneficiary is in a long-term care setting and may result in a recommended medication action plan.
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> * * * * *
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> (D) Standardized action plans and summaries that comply with requirements as specified by CMS for the standardized format.

Therefore, the standardized format is a summary of an interactive CMR that is provided to eligible MTM program members. If MTM providers are performing non-interactive CMRs beyond CMS' requirements, such as in long-term care settings or for unresponsive beneficiaries, the standardized format is not required but could be adapted for use by the provider as needed.

Comment: One commenter asked CMS to confirm that it is permissible to omit the provision of a new (and duplicative) MAP in situations where it is not applicable or necessary for a particular member. Specifically, one asked if the omission of a new (and duplicative) document is not permitted, may plan sponsors complete the top portion of the documents and indicate that the patient should follow previous instructions/lists? This option would eliminate redundancy, facilitate efficiency for sponsors, and provide documentation that the CMR took place.

Response: A new, completed standardized format must be provided to each beneficiary following each CMR. Requiring the beneficiary to refer to previous instructions or lists may be confusing to beneficiaries and affect their ability to comply with current recommendations for their medication therapy.

Comment: One commenter asked whether CMS expects that the standardized format would be sent every time a targeted medication review (TMR) is performed. TMRs are often directed toward prescribers, and in some cases quarterly. TMRs provide no patient or prescriber information. To require this to be sent to the patient every time a TMR is performed may not be practical or provide additional benefit.

Response: The standardized format is only required after an interactive CMR. Use of the standardized format is not required for TMRs, but may be adapted for other uses.

Comment: One commenter asked for clarification on the intent and purpose of the CMR.

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. Refer to Chapter 7 – Medication Therapy Management and Quality Improvement Program – of the Prescription Drug Benefit Manual (http://www.cms.gov/PrescriptionDrugCovContra/12_PartDManuals.asp#TopOfPage) and other related guidance to Part D sponsors for expanded information on the CMR (http://www.cms.gov/PrescriptionDrugCovContra/082_MTM.asp#TopOfPage).

Comment: One commenter suggested that CMS develop a plan/pharmacy instructions document on how the standardized format is to be used and the information that should populate a field.

Response: CMS intends to develop a guidance document that will supplement the "in form" instructions for completion of the format.

Burden

Comment: Two commenters disagreed with CMS' estimate of the resource allocation for the completion of the proposed standardized format due to manual entry of data, researching medication dates, and converting technical terminology to beneficiary-friendly language, such as using the term "high blood pressure" rather than "hypertension." One commenter suggested it will take an additional 15 minutes to research beneficiaries' medication start and end dates and to manually enter data in the standardized format rather than using the plan's current document

templates. Another commenter mentioned that the length of the standardized format would lead to extra printing costs.

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. CMS also included extra printing costs in its estimate of the burden.

Compatibility with Electronic Medical Records

Comment: A few commenters suggested that the information in the documents should be consistent with existing fields in electronic medical records to increase interoperability between healthcare providers. One commenter specifically said this would ensure that completion of the document is driven off existing electronic data elements so that rekeying will not be necessary.

Response: CMS agrees that the standardized format will be supported by electronic medical records, transaction standards, and other databases based on current and developing standards. The forms are a beneficiary-focused output of the interactive CMR; hence the field names may differ from those of EMRs and other HIT. The current domain names/fields on the standardized format were reviewed and tested by Medicare beneficiaries and other stakeholders and reviewed for readability and health literacy. CMS encourages Plan sponsors and MTM providers to develop the crosswalks and dataset transmissions they may need to auto-populate the standardized format.

Flexibility

Comment: Several comments suggested allowing a degree of flexibility in the design, wording, content, and implementation of the format to meet each plan's needs (i.e., providing guidelines for the type of information to be included, but allowing plans/providers to provide the information in their own formats).

Response: The standardized format complies with the requirements of the Affordable Care Act, and will help to assure consistency for beneficiaries across Part D plans. CMS has included a limited degree of flexibility in the standardized format, and encourages plan sponsors to provide supplemental materials to beneficiaries to meet their specific needs.

Sharing Instructions

Comment: There were several suggestions to include instructions to share the documents with caregivers. Comments also suggested ensuring that all three parts of the format contain instructions to share the documents with doctors, pharmacists, and other healthcare providers.

Response: CMS agrees with these suggestions, and has added instructions throughout to share the document with caregivers, and to share the documents with doctors, pharmacists, and other healthcare providers.

Contact Information

Comment: Several responses recommended that the contact information provided on all documents be for the pharmacist or other MTM provider that provided the MTM services.

Response: The name and contact information of the MTM provider are required where indicated on the forms. CMS recommends that the name and contact information of the individual who conducted the CMR be included unless precluded by MTM program structure or procedures. The inclusion of the pharmacist or other MTM provider contact information was also supported in beneficiary testing.

Page Numbering

Comment: One commenter suggested that page numbers be added to the pages.

Response: Page numbers have been added to each section of the standardized format.

Delivery

Comment: One commenter suggested that the patient's primary prescriber should receive copies of the documents. Another recommended sending the documents to all prescribers who treat the patient.

Response: CMS disagrees with these suggestions. The Affordable Care Act requires that the CMR shall include providing the individual with a written summary of the results of the review and does not require a copy be provided to the patient's primary provider. A requirement to always send a copy to the primary care provider (PCP) and treating prescribers would be an excessive burden on plans and MTM providers. The decision to send the documents to the PCP or other prescribers should be determined by the beneficiary, the professional judgment of the MTM provider, or Part D plan. Sponsors are required to provide interventions to both beneficiaries and prescribers, and such interventions should be considered to promote coordinated care.

Comment: Several commenters asked for clarification on how CMS expects the patient to receive the information, for example, via print copy or electronically but preferably using the method the patient prefers. Clarify that pharmacists can complete the documents in electronic format.

Response: In testing, CMS found that beneficiaries and stakeholders had varying preferences for delivery. Distribution of the completed document should be available by hardcopy or electronically via email or web application and subject to the choice of the beneficiary.

Comment: One commenter asked for clarification on the timeframe for delivery of the documents to the patient.

Response: The completed documents should be distributed to beneficiaries within 2 weeks of the CMR. CMS intends to develop a guidance document that will supplement the "in form" instructions for completion of the format.

Form Order (MAP and PML)

Comment: One commenter suggested the PML should precede the MAP. Review of the PML is necessary to discuss the patient's plan of action for each medicine.

Response: CMS agrees that a review of the beneficiary's medications is a preliminary step for development of the action plan. However, for the summary and follow-up activities resulting from the CMR, the recommendations for steps to improve medication therapy should be immediately after the cover letter to help assure that the beneficiary will see it.

Comment: One commenter suggested that combining the PML with the MAP would make the patient's/caregiver's responsibility in the MTM program much simpler.

Response: In testing of the standardized format, beneficiaries and some stakeholders felt that combining the MAP and PML may be confusing and make the medicine list longer. Overall, CMS determined that it was appropriate to keep the two documents separate.

Length/Layout (MAP and PML)

Comment: Several comments suggested that the current formatting is not desirable as it significantly lengthens the document for the member.

Response: CMS disagrees with this suggestion. The current formatting is designed to make the documents more accessible to Medicare beneficiaries, which requires greater length to accommodate a larger font size and more white space in order to improve the readability.

Comment: Several commenters suggested the MAP length should be limited to one page (front and back is acceptable). To be useful, patients need to fold up the page and carry it with them in their purse or wallet.

Response: CMS understands the desire to limit the length of the MAP and other documents, but disagrees with choosing an arbitrary length. The number of action items for a given beneficiary will determine the length of the MAP, as well as formatting appropriate for the target population (e.g., font size, white space, etc.). In addition, the MAP is not a "wallet card," which is available from other sources.

Comment: Several commenters indicated that the main content of the MAP and PML should be presented as a table, to include one row for each item, rather than stacked columns.

Response: Health literacy guidelines suggest that "chunking" this type of material 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.

Comment: Several comments suggested a landscape orientation. Some of these suggested allowing plans to use either landscape or portrait layout.

Response: In consumer testing, beneficiaries preferred the current portrait orientation. Stakeholders also submitted public comments in support of the portrait or vertical orientation. In

addition, a landscape, single-row tabular format does not accommodate the required number of fields with 14-point font.

Content (MAP and PML)

Comment: One commenter suggested that the current design of the MAP and PML do not include desired data elements that should be included in the materials.

Response: CMS disagrees with this comment but appreciates the commenter's desire to provide more information to beneficiaries. The standardized format to summarize the interactive CMR was developed based on extensive research, input from stakeholders, and testing with beneficiaries. The MAP allows flexibility of content in the issue field, and the PML provides an optional field for plans to include other data elements. Plans and providers are also encouraged to augment the standardized format with supplemental information to meet the needs of the beneficiary. The addition of other data elements will be considered for future revisions of the format.

Headers and Footers (MAP and PML)

Comment: A few comments suggested requiring headers and footers only once for each document type: headers on the first page of the MAP and PML, and footers with plan/provider messaging (e.g., marketing statement, privacy statement) on the last page of the MAP and PML.

Response: CMS agrees with this suggestion except the inclusion of marketing statements. A header with plan/provider identification must be included on the first page of the BCL, MAP, and PML. The CMS-required footer with the CMS form number and OMB approval number and the Paperwork Reduction Act statement must be included on the pages where indicated. Plan-specific privacy statements are not required, but may be included on the last page of the BCL, MAP, and PML, above the CMS-required footer and PRA statement. Marketing messages and other sales information should not appear anywhere in the standardized format. CMS will provide further clarification in the guidance for users.

Beneficiary Identifiers (MAP and PML)

Comment: Two commenters recommended creating a separate box/section at the top of the MAP and PML highlighting the key member identifiers (e.g., name, date of birth, member ID number).

Response: The standardized format has been revised to require only member name and date of birth. To improve readability, this information is now included in a text box on the MAP and PML. Additional space is available to include other member identifiers on the BCL.

Other Comments

Comment: One commenter suggested that it may be challenging for some participants to add to the PML or bring the MAP with them to the hospital or emergency room. The text should emphasize that these documents are intended as a helpful tool but are not a mandatory exercise.

Response: The documents encourage program participants to use the forms as helpful tools and do not indicate that it is mandatory. CMS does not see the need to specifically state that the suggested actions and plans are not mandatory. The voluntary nature of the MTM program is included in other program documents.

Comment: One commenter asked for clarification about whether there are space/character limitations for the fields to be populated in the standardized format.

Response: CMS will not place space or number of character limitations for data to be entered into the standardized format. A 14-point serif font is required for content of the BCL, MAP, and PML, and minimum sizes are required for fields that beneficiaries will complete. CMS intends to develop a guidance document that will supplement the "in form" instructions for completion of the format.

Comment: Because the MTM program is delivered on an opt-out basis, the notice should inform participants that their participation in the program will not be used in any way to their detriment by their Part D plan. For example, MTM should not be used to switch a participant to a different drug in the absence of a consultation between the prescriber and patient

Response: CMS disagrees with this comment. The standardized format is a summary of the CMR, not a notice about the MTM program. Although the message that participation in the MTM program will not be used to the beneficiary's detriment by their Part D Plan may be reinforced during some CMRs, CMS does not see the need to include it as a required element of the standardized format. Furthermore, the Affordable Care Act specifies that the CMR shall include a review of the individual's medications and may result in the creation of a recommended medication action plan or other actions in consultation with the individual and with input from the prescriber.

Comment: One commentor suggested including an option for populating fields with standardized text choices versus free text.

Response: CMS considered and rejected this option because a standardized set of text choices would limit the ability of the MTM provider to tailor the information to the specific needs of the beneficiary. As CMS gains more experience with MTM and CMRs, it may be possible to implement this suggestion to some extent in the future.

II. Beneficiary Cover Letter (BCL)

Support for the BCL

Comment: Several commenters expressed support for the content of the BCL, including that it is much improved, simplified, more streamlined and beneficial than the original version; it is very good since the summary section was removed; and keeping it to one page is much better. Another commenter thanked CMS for incorporating previous suggestions from stakeholders.

Response: CMS appreciates all the comments and support from stakeholders, and their desire to improve the standardized format for the benefit of beneficiaries.

Content and Wording

Comment: There were numerous suggested wording changes to add or delete selected words, phrases, and/or sentences. Some of the suggestions included adding bullets or changing the tense on portions of the letter, and adding information to the message that should be conveyed.

Response: Recent revisions to the documents are based on research including input from commenters, stakeholders and testing with prescribers, providers, plan sponsors, and beneficiaries. Some of the suggestions received during the comment period are in agreement with revisions that have been made as a result of stakeholder input. Additional changes have been made based on a review of the literacy level and readability of the letter. Other changes suggested by commenters will be considered for future revisions to the standardized format.

Comment: One commenter suggested presenting the instructions in the third paragraph in bulleted form. This paragraph instructs the beneficiary to take the documents to appointments and share them with healthcare providers.

Response: These instructions have been converted to a bulleted list.

Comment: One commenter asked for clarification on the intended use of the "< Additional Space for Plan/Provider Use >" space at the top of the letter. Specifically, indicate that it is not to be used for marketing messages or other sales information.

Response: CMS agrees that this section, as well as the entire standardized format, is not to be used for marketing messages or other sales information. The instructions for this section have been revised with examples of appropriate, optional content. This section of the BCL may be left blank.

Comment: One commenter asked: Within the body of the BCL, is all the language provided in the template required? Specifically, in the last paragraph, is telephone number sufficient, or do we need to provide "days/times, TTY, etc?"

Response: During testing, beneficiaries indicated 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 and should be included in addition to the telephone number. CMS encourages Plan sponsors to include all information that will be relevant to the Plan's beneficiaries, such as availability of text telephones and language translation services.

III. Medication Action Plan

Support for the MAP

Comment: Several commenters acknowledged the simplicity, flexibility, and patient-friendly format and content of the MAP, including the field titles. One commenter thanked CMS for incorporating previous suggestions from stakeholders.

Response: CMS appreciates all the comments and support from stakeholders, and their help to improve the standardized format.

Overall

Comment: One commenter suggested making this document a summary of the highlights of the medication counseling session and listing items that need follow-up without requiring that exact "boxes" be completed.

Response: CMS understands that there are many different ways to present the content of the forms. However, the boxed format was chosen because beneficiaries preferred it during testing.

Comment: One commenter recommended reformatting the entire MAP as a checklist to reduce white space and minimize paper usage.

Response: CMS disagrees with this suggestion. The required use of a checklist would limit the ability of plan sponsors to customize the information to the specific needs of beneficiaries. Plan sponsors may use checklists within the MAP fields, but are not required to do so. Further, health literacy guidelines suggest 10 to 30 percent of the page should be white space.

Content

Comment: Three comments suggested consolidating the boxes “What we talked about” and “What I need to do” into one box entitled, “What we talked about and what I need to do.”

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

Comment: One comment suggested replacing the text box “What I did and when I did it” with a checklist of items to be completed as they are accomplished.

Response: CMS disagrees with this suggestion. CMS prefers to leave this field blank to reduce the burden on plan sponsors. Plan sponsors may use checklists within this field, but are not required to do so, and should allow flexibility for the beneficiary’s response.

Comment: One commenter suggested adding a text field, “Problems I am having with this medicine” and including a related Action Step, as necessary.

Response: For new problems since the CMR, beneficiaries can include this information in the “Questions I want to ask” box, and related action steps can be captured in the “My follow-up plan” box. These boxes have replaced the space previously provided for “Additional Information.”

Comment: One comment included a recommendation to include in the MAP a checklist of the most common topics the pharmacist might discuss with the plan member, such as adverse events, use of non-prescription medications or supplements, health status, medication history, disease management programs, etc.

Response: CMS disagrees with this recommendation. The topics the MTM provider should discuss with the beneficiary are included in training of MTM providers based on industry standards, and may be included in the MTM provider’s worksheets. Including a list of these topics in the MAP would increase the length of the MAP needlessly. The MAP is intended to summarize the CMR consultation and recommended action steps for the beneficiary and is not intended to be a discussion checklist for the provider. These items can be individually addressed

in the existing text fields, and this method of addressing them allows for additional details, specific action steps, etc., rather than a simple checklist. CMS is analyzing best practices and will consider specifying the goals of interventions and the process of care, such as service level expectations for a CMR in the future.

Comment: One commenter suggested including information in the MAP informing plan members of their rights regarding formulary and tiering exceptions.

Response: CMS believes that this topic is better addressed in other communications with beneficiaries concerning benefit design, but may be addressed during the CMR. CMS is not currently defining the specific topics for the CMR.

Comment: One comment asked CMS to consider that one conversation may have three to four action items. Therefore, it may not be necessary to repeat "What we talked about" multiple times. This respondent suggested including multiple bullets under "What I need to do."

Response: CMS understands that a single conversation may produce several related action items. However, CMS would like to provide space for several topics as well, recognizing that each topic may include several items in the "What I need to do" box. The current standardized format allows for both scenarios.

Comment: Two commenters suggested deleting the text box "Additional Information."

Response: Recent changes to the MAP based on stakeholder and beneficiary testing include removing the "Additional Information" field and including two new fields for beneficiary use: "My follow-up plan" and "Questions I want to ask."

Comment: One commenter suggested that there may be cases where there is no actionable item other than to reinforce current behaviors and proposed using a standardized statement reinforcing compliance.

Response: CMS recognizes that there may be no action items for a given discussion. The standardized format allows plan sponsors to enter other statements as appropriate, such as reinforcing compliance, maintaining beneficiary's actions, and acknowledging beneficiary success in their medication therapy.

Comment: One commenter recommended putting in boxed text the reminder "If you have any questions" along with the contact information for the MTM provider.

Response: CMS has made further revisions to the MAP based on a review of the literacy level and readability of the format. Who to call with questions and the MTM provider's contact information has been moved to the end of the MAP.

Comment: One commenter said that the MAP does not have a box to indicate which medications were identified for the clinical issue. This will confuse both members and providers if not specified. The commenter recommend adding a box above "What we talked about" for "Medications involved" to identify key medications that cause the clinical issue to be identified. For gaps in care issues, populate with "none."

Response: 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 medication or care issue

within the “What we talked about” box, such as to list the medication first in the box or add emphasis to that specific text. Adding more text boxes would also lengthen the MAP.

Wording

Comment: One comment suggested revising the “What we talked about” field title with one that reflects the medical condition or body part related to the action.

Response: CMS disagrees with this suggestion because every action item may not be related to a specific medical condition or body part/system, and some actions may be related to more than one body part and system. As mentioned previously, the MTM provider has the discretion to choose how to make reference to the care issue within the “What we talked about” box.

Comment: One commenter suggested adding to the instructions a third bullet that plan members may–but do not need to–complete the “What I did” box, and to further state that the form is for their own personal education and use.

Response: CMS disagrees with this suggestion because the documents should encourage program participants to use the forms as helpful tools, to complete the MAP and also use it when engaging with their healthcare providers as part of the overall goal of the MTM program.

Comment: One commenter recommended modifying the bulleted instructions in the following way: “Review the ‘What we talked about’ section below,” “Review the ‘What I need to do’ sections below,” “Once you have taken action, fill in ‘What I did and when I did it’ section.”

Response: CMS appreciates these suggestions and will consider changes to the instructional language in future revisions of the standardized format.

Instructions to Users (Plans and Providers)

Comment: One commenter suggested that the section "What we talked about" should reference treatment goals or patient goals rather than just a description of the topic.

Response: CMS agrees that it is important for beneficiaries to understand their goals of therapy. Whether or not to specifically include the goals of therapy in the issue field is a choice of the MTM provider and MTM program based on the discussion during the CMR and needs of the beneficiary.

Comment: One commenter recommended that the "What I need to do" field recommend including patient instructions–such as “patient to follow up with MD” or “pharmacist to follow up with MD”–to avoid confusion over next steps in the process.

Response: The primary intent of this field is to include action steps for the patient, not providers. However, it may be appropriate to mention follow-up by the MTM provider in certain situations. Whether or not to specifically include the provider’s next steps in the process is a choice of the MTM provider and MTM program based on the discussion during the CMR and needs of the beneficiary.

Comment: One commenter suggested prioritizing, and listing in present-tense, the Action Steps in the “What I need to do” field.

Response: Health literacy guidelines suggest the use of concrete nouns and active voice, as well as presenting the most important information first. CMS supports this recommendation and will address it in the guidance for users.

Comment: One commenter suggested that the number of discussion topics should be limited to between three and five.

Response: CMS disagrees with this suggestion, and understands that a beneficiary may be more motivated to address a smaller number of action items at any given time. The MAP is a summary of all the action items discussed during the interactive CMR. MTM providers use their professional judgment to determine which action items to discuss based upon the needs and concerns of the beneficiary at the time of the CMR.

Other

Comment: Four comments noted a need for flexibility on the form to allow for actions associated with specific drugs.

Response: The form in its present state allows flexibility for actions related to specific medications to be documented, and those specific medications can be referenced in the "What we talked about" box. CMS does not expect every discussion point and related action item(s) to necessarily be associated with a particular medication, and some may be associated with more than one medication.

IV. Personal Medication List

Support for the PML

Comment: Many commenters indicated support for the PML, including terminology, field titles, removal of the "Goals of Therapy" (which appeared on the previous version), and keeping the additional information field for other notes.

Response: CMS appreciates all the comments from stakeholders and their support of the standardized format and its value to beneficiaries and MTM programs.

Allergies and Side Effects Box

Comment: For the "Allergies and side effects" box, provide guidance that the name of the offending medicine should be accompanied by what happens when the patient takes the medicine. Clinicians will be able to distinguish between allergies and side effects. Patients do not always make this distinction and will understand it as what happens when they take certain medicines.

Response: The instructions for this field currently indicate that the products and their effects should be included. This will be further clarified in the guidance for users.

Comment: One commenter recommended changing "Allergies and side effects" to "Allergies and adverse effects."

Response: CMS disagrees with this recommendation. "Adverse effects" is not simple language that will be understood by many beneficiaries. The intent of this field is to capture medications that a beneficiary cannot tolerate or that cause discomfort due to allergy or specific side effect, rather than the general side effects of the medications listed. This will be clarified further in guidelines for the use of the format.

Comment: Six commenters suggested having allergies and side effects as two separate fields.

Response: This field is meant to capture the beneficiary's medication-related side effects and allergies. Many beneficiaries do not distinguish between these two categories, but group them into a general category of effects of medicines. For this reason, CMS will leave this as one field.

Start/Stop Date Boxes

Comment: Many commenters recommended deleting the start and stop date fields. A few of these said that, at a minimum, the date stopped field should be left blank and identified for patient use. Providers should have some flexibility in how or whether they fill out that element. One suggested replacing these fields with checkboxes that indicate current or discontinued medications.

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 start dates if known or based upon beneficiary-reported data, or leave blank for beneficiary to enter. This will be clarified further in guidelines for the use of the format.

Comment: Two comments indicated that the field "Date I started using it" should be revised to "Date I filled the medication" or "Date I last filled the medication" to allow for automatic claims data population and the fact that beneficiaries often do not remember when they started using a medication.

Response: CMS disagrees with this suggestion. Prescription fill dates are useful for compliance analysis in preparation for the CMR, but are not meaningful for the PML. The last prescription fill date will be quickly invalid based on annual CMRs. In addition, the "Date I started using it" accounts for lag in fill time and for the prospect of alternate scenarios (e.g., a physician provides a limited supply of the medication at the time of the visit).

Comment: One commenter asked CMS to consider revising the "Date I started using it" to say something like "When I started using it."

Response: CMS appreciates this suggestion to make the field title less specific in order to account for beneficiaries who do not recall the exact dates they started a medication. To account for this, guidance will be provided to indicate that information in this field may be estimated. CMS will consider this change for future revisions of the PML.

Comment: The start/stop date issue brings up a concern about the scope of look-back of the CMR counseling, and commenters questioned if the intent of CMR is to counsel patients on current use of medicines or historical use of medicines. For counseling purposes, a 60- to 90-day look-back should be adequate. For adherence and persistence determinations, a medication history of 180 to 360 days may be needed to capture all the 90-day prescription fills and refills.

Response: The PML should capture medications currently in use at the time of the CMR. CMS suggests a minimum look-back of 6 months to identify current medications and prescribers, and for utilization review. Regardless of look-back period or availability of historical data, the interactive CMR is an opportunity to capture data from the beneficiary, including current medications, OTCs, other unreported medications and beneficiary concerns.

Prescriber Information

Comment: Two commenters suggested deleting the name of the prescriber under each medication.

Response: CMS chooses to retain this field. For beneficiaries with multiple prescribers, it provides a record of who gave the order. It would also be helpful for healthcare providers who review the list to know the specific prescriber to ensure better coordination of care.

Comment: Two commenters recommended adding a section that identifies the patient's primary prescriber and emergency contact information.

Response: Some beneficiaries do not have a consistent primary prescriber. For this reason, space is provided for the name of the prescriber of each medication. MTM providers may include the identity of the primary care prescriber and emergency contact information in the "Additional Information" field.

Comment: One commenter suggested revising the prescriber field to say "prescriber and phone number."

Response: MTM providers may include the prescriber's contact information, but it is not required. CMS chooses not to require the prescriber's contact information to be included for each prescriber because this information may not be available at the time of the CMR and it may add to the research time involved in completing the PML.

Content

Comment: One commenter suggested adding space to capture OTC medications and herbal products.

Response: OTCs are already captured in the medication list. Herbals have been added to the list of medications to include on the PML. In order to remain consistent with the goal of helping beneficiaries manage all of their medications, non-prescription medicines will be included in the main section of the PML with prescription medications. Plan sponsors and their MTM providers may choose the order of products in the PML, such as based upon indication or other criteria.

Comment: One commenter suggested that the prescriber field should be populated with "self" when OTC medications are self-prescribed.

Response: If an OTC is ordered by a prescriber, the PML should indicate the name of the prescriber, even if reported by the beneficiary. Otherwise, for non-prescribed OTCs, enter "self" in the prescriber field or leave it blank. CMS will address this in guidance to users.

Comment: One commenter suggested adding a field to reflect whether any monitoring tests are required and the frequency of such tests.

Response: If the beneficiary needs to be reminded to comply with monitoring test requirements, this information is captured in the MAP and is thus not needed on the PML. Plan sponsors and MTM providers may include information about routine monitoring tests in the "other titles field" of the PML if desired.

Comment: Three commenters recommended deleting the text box "Additional Information," as it is unnecessary for this document and could be confusing to the patient.

Response: CMS disagrees with this recommendation. In testing, consumers and stakeholders agreed that this was a good place to record any important information not captured elsewhere on the form. Such uses may include but are not limited to the primary care provider, emergency contact information, primary pharmacy, and list of beneficiary's conditions that are not listed elsewhere.

Comment: One commenter suggested that it seems less useful to include short-term medicines for acute conditions on the PML. For example, a patient may have skin eruptions from poison ivy dermatitis and be in the midst of a steroid taper. To include medication of this nature on the PML does not serve a long-term purpose. Should MTM counseling and related documents emphasize (or be exclusive to) long-term use of medicines for chronic diseases?

Another commenter suggested that listing chronic medications should be the top priority, followed by other medications to which the Part D plan has access. Plans should have flexibility to determine how much data to include. Plans should have the option to list historical drug use on the PML, when appropriate.

Response: The standardized format is a summary of the comprehensive medication review of all the beneficiary's medications. Therefore, the PML is a record of all medications being used by the beneficiary at the time of the review, including chronic and acute, legend and non-legend, and vitamin, mineral, and herbal supplements. Further, management of medication therapy and prevention of adverse drug events requires that the PML include all medications. The PML includes instructions for beneficiaries to record when medications that are discontinued.

Plans are encouraged to supplement the PML with additional information to benefit the beneficiary. This may include historical drug use at the Plan's option.

Comment: Two commenters suggested adding a bullet "Review list below for accuracy and completeness" to the instructions at the top, and deleting "and fill in the dates you stopped using them" from the second bullet.

Response: CMS will consider adding instructions for the beneficiary to review the list for the next revision of the standardized format. The format currently provides instructions to the beneficiary to keep the list up to date, such as add new medications or cross out discontinued medications.

CMS disagrees with the second suggestion because beneficiaries and other stakeholders indicated during testing that the date a medication was stopped is important.

Comment: One commenter asked that CMS clarify the second bullet so that the sentence reads, "Cross out medications when you are no longer using them and fill in the dates you stopped using them so that your medication list can be updated."

Response: Based on testing and literacy/readability review, CMS has changed the format to emphasize the importance of updating the list. CMS will consider this suggestion for the next revision of the standardized format.

Comment: One commenter thought the "Why I use it" section is difficult to fill out, especially when forms are created electronically based on medical claims data. If possible, the beneficiary should fill in the information where there are opportunities to do so. The commenter also suggested noting the information as "patient reported" in case the patient remembers incorrectly and was concerned about incorrect information being carried through the medical system.

Another commenter suggested that "How I use it" is a liability concern because members may give inaccurate information.

Response: MTM providers may use several strategies to acquire the required information, and the forms should not be created using claims data alone, but include information gathered during the interactive CMR. The sources of information for the PML will be clearly stated in the first paragraph of the PML and this may include the beneficiary. Regardless of data source, the interactive CMR includes discussion of these data elements, with an opportunity to check with the beneficiary for current/updated information and non-reported medications. 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.

All healthcare providers receive patient-reported information. The plan or MTM program may identify specific beneficiary-reported information in its own records. However, the standardized format does not include specific identifiers for self-reported data.

Comment: One commenter suggested that action steps be prioritized and listed in present tense at the top of the PML.

Response: The PML includes instructions for the beneficiary in priority order and listed in present tense at the top of the PML.

Comment: Two commenters suggested eliminating all but the most basic information, such as medication name, when it is taken, how it is taken, and prescriber name.

Response: CMS disagrees with this suggestion. Necessary and important data elements are captured in the standardized format, based on the formative research and testing completed to date.

Comment: One commenter suggested that the instruction "Use blank rows" could be very confusing.

Response: CMS appreciates this concern, and believes that this instruction will be clear within the context of the PML and with guidance from the MTM provider. CMS will continue to explore ways to increase awareness of beneficiaries about MTM programs and how to effectively use the forms.

Comment: One commenter suggested that the "Why I use it" field be considered in relation to sensitive diagnoses (e.g., HIV/AIDS) and proposed using a statement instructing the beneficiary to consult their healthcare provider with questions about why they are taking a medication. Stating a sensitive diagnosis in the letter could potentially cause concern with beneficiaries.

Response: CMS appreciates this concern. All health care information is sensitive and subject to privacy protections. The standardized format, including diagnoses and other personal health information, is being delivered to the beneficiary after discussion during their CMR. All applicable healthcare information from the CMR should be included in the forms unless specifically directed otherwise by the beneficiary.

Organization

Comment: Five commenters suggested that medications should be grouped under a primary chronic disease header for easy review.

Response: CMS considered this option, but stakeholder feedback suggested that (a) it would be difficult to implement using methods that automatically populate fields, and (b) medications that apply to more than one condition would be difficult to place. Alternatively, plan sponsors and MTM providers may choose to sort the PML by condition.

Comment: One commenter recommended inserting "Why I use it" before "How I use it" so that it provided more clarity to the beneficiary.

Response: CMS disagrees with this recommendation. Various stakeholders, including beneficiaries, indicated that having "How I use it" (e.g., one tablet once daily) after the name of the medication and strength was consistent with the presentation on a prescription label. The purpose of the medication is usually at the end of the directions (SIG) on prescription labels, if included.

Wording

Comment: One commenter suggested changing the text of "How I use it" by revising it to say "How and when I use it" to help ensure that the patient knows it refers to how and when they take their medications.

Response: Revised instructions for completing the PML indicates that the "How I use it" field should be filled with information on dosage, strength, frequency, and other supplemental instructions. The medication schedule will be clear to beneficiaries based on completed information. CMS will consider the suggestion for a future revision of the standardized format.

Instructions to Users

Comment: One commenter suggested clarifying that the text to populate "Insert sources of information" should indicate the patient, pharmacist, physician, pharmacy records, etc. that provided the information to populate the list.

Response: CMS agrees with this suggestion and will provide further clarification in the guidance for users.

Comment: One commenter asked for clarification on the intent of the "Insert other titles" field.

Response: The title and content of this field are defined by plans/providers to allow flexibility of information provided. This field is intended to capture other medication-related information that plans/providers prefer to include in a medication list, such as images of medications, goals of

therapy, other product identifiers, and supplemental instructions. The title of this field must be changed to reflect its content. Plans/providers may choose not to include this other information and must delete the field if not used. CMS will provide further clarification in the guidance for users.

Comment: One commenter suggested populating the "medication" field using the label name of the product they are taking.

Response: CMS disagrees with this suggestion. Merely including the label name of the product is not sufficient. Revisions have clarified the instructions for this field to include generic and brand names of the medication, strength and dosage form. CMS will provide further clarification in the guidance for users.

Other

Comment: Clarification of the intent and purpose of the PML is requested.

Response: The PML is intended to provide Medicare beneficiaries with a list of their current medications, to help Medicare beneficiaries understand their medications and how they relate to their treatment plans, to engage beneficiaries in the management of their drug therapy, and improve communication as well as tracking of all medications, including self-prescribed medicines, with their various healthcare providers.

Comment: One commenter suggested that the PML be included in the annual "Medicare and You" handbook as an insert that can be easily removed by the consumer. Regardless of whether Medicare beneficiaries are Part D enrollees and MTM-eligible, they can all benefit from keeping a PML.

Response: CMS appreciates this suggestion and agrees that all Medicare beneficiaries may benefit from keeping a PML. CMS will consider this recommendation for future implementation.