

## **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 comments was posted in the *Federal Register*, Vol. 79, No. 12, on January 17, 2014. During the 60-day comment period, 16 comments were received from three organizations.

CMS has engaged stakeholders throughout the development of the Standardized Format and appreciates their comments and suggestions in response to the request for comments. CMS' responses to comments 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: Two commenters expressed support for the proposed changes to the Format, including appreciation that the proposed changes are minor revisions to a still newly created document/process, and that the Format is an important tool for ensuring service-level expectations and standards of practice for a comprehensive medication review in the Medicare Part D MTM program.

Response: CMS appreciates the comments that support the revisions to the Format and its value to Part D MTM programs, and the suggestions submitted by stakeholders.

### **Burden**

Comment: One commenter suggested that the burden estimate should be increased because incompatibility of the Format with EHR platforms can increase the time required to complete documentation of each CMR by up to 20 minutes. The commenter also stated that the MAP is not compatible with electronic health record platforms used by qualified providers or pharmacists to document the comprehensive medication review, and urged CMS to consider taking steps to align the Format with EHR platforms.

Response: CMS appreciates the commenter's support for the use of EHR platforms to document CMRs, and disagrees with the statement that the Format is incompatible with EHR platforms. Standard data elements are available to incorporate the requirements of the Format into EHR systems, as evidenced by work of the NCPDP WG10 MTM Task Group and the Pharmacy e-HIT Collaborative. CMS continues to encourage sponsors and MTM providers to use standard elements in databases and EHRs rather than manipulating free-form text documents, which may require upgrades to their EHR platforms and training of personnel. The burden estimate considers the average time to conduct CMRs, which may vary based on the complexity of the

individual case or plan sponsor or provider efficiencies. However, in recognition that some sponsors have not yet transitioned to using the standard elements or EHRs to fully document CMRs, CMS increased the burden estimate by 5 minutes for each CMR.

### **Length/Layout (MAP and PML)**

Comment: One commenter stated that the Format is too long and contains too much information, particularly the MAP and PML, and is cumbersome for beneficiaries to maintain and carry with them to their other healthcare visits.

Response: CMS appreciates the concern that complying with the Format results in long CMR summaries. CMS conducted testing in the development of the Format and is aware that some beneficiaries would also like a single “wallet” card that lists their medications for quick reference and easy carriage. CMS considered adding a wallet card to the Format, but limited the current proposed revisions to the Format to prevent increasing the length of the CMR summary. More extensive revisions to the Format, including specifications that may shorten the Format documents and the addition of a wallet card format, will be considered in the future.

### **Flexibility**

Comment: One commenter recommended that CMS could standardize the elements that must be included in the Format and provide flexibility for Part D sponsors to format this summary in a manner that better aligns with their beneficiary feedback.

Response: CMS disagrees with this recommendation. The 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 Format, and encourages plan sponsors to provide supplemental materials to beneficiaries to meet their specific needs.

### **Terminology**

Comment: One commenter suggested that the tone reflected in the Format may be interpreted as too directive and not respectful of the ability of beneficiaries to take responsibility for their medications.

Response: CMS appreciates the commenter sharing this perspective and concern for beneficiaries. The current wording of the Format is intended to encourage the recipient to take action to understand and use their medications correctly, resolve any problems with their medication therapy, and achieve the best medication outcomes. CMS understands that beneficiaries’ ability and need to do so will vary. Prior testing, including testing with beneficiaries, indicated that the current text is acceptable and did not support a need for significant revision. Additional revisions to the Format, including the tone of the text, will be considered in the future.

## **II. Beneficiary Cover Letter (BCL)**

### **Support for the BCL**

Comment: One commenter appreciated the flexibility that is proposed in the logo placement, which will allow the logo selected by the plan sponsor to be visible through the envelope window.

Response: CMS appreciates all the comments and support from stakeholders and their desire to improve the Format for the benefit of Part D enrollees.

### **Content and Wording**

Comment: One commenter was concerned that the required addition of the reference to translation services would push the Cover Letter to two pages with the given specifications. To keep the length limited to one page, the commenter suggested that CMS consider options such as reducing the margin specifications to help allow more text on the Cover Letter.

Response: CMS notes that MTM materials are not subject to translation requirements and will remove the required translation statement rather than making other formatting changes at this time. However, CMS continues to encourage Part D Plans to offer and provide translations of the Format as needed to satisfy the language needs of their beneficiaries.

## **III. Medication Action Plan (MAP – see Burden and Length/Layout comments above)**

## **IV. Personal Medication List (PML)**

### **Content**

Comment: One commenter recommended that goals of therapy should be included for each medication of the beneficiary. The commenter stated that establishing specific goals of therapy for each of a beneficiary's medications has been shown to be a central element for improving care at reduced per capita expenditures. Requiring goals of therapy, in addition to current requirements for stating the indication or intended medical use of each medication in the Format is consistent with service-level expectations specified in CPT and supported by results from best practices.

Response: CMS reminds sponsors that the Format currently provides flexibility for the goals of therapy to be included in the PML. Additional revisions to the Format, such as the addition of goals of therapy in the PML, will be considered in the future.

### **Organization**

Comment: One commenter recommended that CMS permit sponsors to utilize either a portrait or landscape layout, suggesting that a landscape layout can accommodate information on a larger

number of drugs on a single page, reduce the length of the Personal Medication List, and make it more beneficiary-friendly and easier for providers to review.

Response: In CMS' prior testing, beneficiaries indicated that the portrait orientation is preferred over landscape for Format documents. Additional revisions to the Format, including landscape orientation, will be considered in the future.