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Medication Therapy Management Program Improvements—Standardized Format. (CMS-10396)

Comment On: CMS-2011-0113-0001
Medication Therapy Management Program Improvements—Standardized Format. (CMS-10396)

Document: CMS-2011-0113-DRAFT-0014
DC

Submitter Information

Name: Jane Galvin
Address:
Washington, DC, 20005
Organization: BlueCross and BlueShield Associaton

General Comment

Attached are comments on the MTM Standardized Format from BCBSA

Attachments

Medication Management Form, Final Auguat 1lst

BlueCross BlueShield Association

An Association of Independent Blue Cross and Blue Shield Plans

1310 G Street, N.W.
Washington, D.C. 20005
202.626.4780
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August 1, 2011 (DRAFT)

Mr. Gary Wirth

The Centers for Medicare and Medicaid Services

Re: Form Number CMS-10396 (ONC:0938-NEW)

Filed at: www.Regulations.gov

Dear Mr. Wirth:

Thank you for the opportunity to provide additional comments on several documents slated to be adopted for use in the Medication Therapy Management Program, Medicare Part D. These forms are collectively referred to as "Medication Therapy Management Program Improvements-Standardized Format" and are to be used to provide a written summary of the interactive comprehensive medication review conducted by a pharmacist or other health professional with an individual Part D beneficiary.

As you know, BCBSA filed comments on the first draft of these forms with CMS on March 25, 2011. We appreciate that some modifications were made as we had suggested in our initial correspondence. However, we believe that these forms require further revisions to make them useful for the beneficiary and meaningful to the medication evaluation process.

One important point for consideration is that much of the information needed for the completion of these forms must be manually compiled and inserted. Part D Plans do not have systems in place to pre-populate these forms from their pharmacy systems. This creates a time and task burden and staff resources need to be taken into consideration. Medication management evaluations are critical to improving drug use and avoiding drug interactions. We would not want to have standards in place that require the pharmacist or other health care professional who is meeting one-on-one with the beneficiary to devote most of his/her time to completing these forms rather than spending the allotted time counseling the patient, which is the priority of this activity. The focus needs to be on the interactive consultation, not the forms.

Overall, the forms capture a number of important items. We have concerns, however, with the suggested formats, especially for use by disabled and elderly beneficiaries who have multiple chronic conditions and a high level of medication use. We believe more flexibility is needed with these formats—as long as required information is presented. Part D Plans should have the ability to format this data in a manner that suits the needs of their beneficiaries.

Therefore our major recommendation is to have these forms kept as simple, readable and useful as possible. These revised drafts do not meet these objectives – as these proposed letter and forms could end up being some 10 to 12 pages long, not a useful tool for any beneficiary.

We will address each of the three forms separately:

The Beneficiary Cover Letter (also labeled as "Attachment")

- In the third paragraph we suggest changing the first sentence to read: "Share your Medication Action Plan and Personal Medication List with your doctors, your pharmacists, and other healthcare providers" Adding reference to pharmacists would be appropriate here.
- We believe this cover letter needs to meet a health literacy standard for the average Medicare beneficiary.
- Focus group testing of this cover letter is recommended.

Personal Medication List

- This form needs to be simplified so that it is more of a summary / reference list for the beneficiary.
- Numbers should be added to the pages
- Listing chronic medications should be the top priority, followed by other medications that the Part D Plan has access to. 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. Plans may have limited drug history information in some cases, particularly with newly enrolled beneficiaries.
- Since all of the information to be added to this medication list will be pulled from primarily from prescription claims, we suggest deleting the "start" and "stop" dates as these data elements are not found in claims. Further, in some cases such dates could add to beneficiary confusion. To be most useful, the medication list should be current as of the date it was complied.
- Delete the name of the Prescriber under each medication as this also might add to beneficiary confusion. Different prescribers might prescribe the same medication. An alternative would be to list all the providers that the Plan has in its records of prescribing medicines to capture this information without actually assigning a prescriber to each medication.
- Would recommend inserting "Why I use it" before "How I use it" so that it provided more clarity to the beneficiary.
- Patients also may also take over-the-counter medications as well as herbal products. There should be a place for beneficiaries to self-report / record these items on their medicine list.
- Keeping the suggested "Additional Information" is an appropriate field for additional notes.
- The format needs to be concise; the literacy level needs to be evaluated; and the terminology focus needs to be tested to be sure the average Medicare patient can understand this document.

- It is unrealistic to require a standardized format that ends up being a “small book.” The format needs to be consolidated to make this a useable document, even for the beneficiary using a lot of medicines.

Medication Action Plan

- The suggestion is to make this a summary where the pharmacist would recap the highlights of the medication counseling session and list items that need follow-up without requiring that exact “boxes” be completed.
- The following examples demonstrate the need for flexibility on this form: a) the beneficiary may be advised to get a flu shot and the action would involve the beneficiary interacting with the physician or immunization clinic; or, b) the beneficiary could be advised to speak to the doctor about daily weights. Also, this section needs to be flexible enough to allow for actions associated with specific drugs. The majority of Interventions will be tied to specific drugs.

Thank you again for the opportunity to provide comments on these forms. Questions on these forms may be addressed to my office at Jane.Galvin@bcbsa.com

Sincerely

Jane Galvin
Managing Director
Regulatory Affairs

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Comment On: CMS-2011-0113-0001
Medication Therapy Management Program Improvements—Standardized Format. (CMS-10396)

Document: CMS-2011-0113-DRAFT-0015
MA

Submitter Information

Name: Keith Greiner
Address:
Worcester, MA, 01608
Organization: Fallon Community Health Plan

General Comment

We feel that this standardized form should address what would happen in the event of a plan sponsor not being able to reach a member after multiple attempts or what would happen if a member declines interactive portion but he/she doesn't opt out of the program entirely? If one of these scenarios happens then this sentence in the standard form which reads "On < insert date of service >, < we talked/you talked with _____ > about your health and medications you're taking" would not be valid. Does the agency expect plan sponsors to send a written summary of the medication review to the member in this scenario?

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Medication Therapy Management Program Improvements—Standardized Format. (CMS-10396)

Document: CMS-2011-0113-DRAFT-0016
AZ

Submitter Information

Name: Melanie Merlino
Address:
Scottsdale, AZ, 85260
Organization: CVS Caremark, Silverscript (S5601), RxAmerica-Accendo (S5644), CCRx (S5803, S5825)

General Comment

Please find these comments that are being submitted on behalf of CVS Caremark, Silverscript Insurance Company (S5601), RxAmerican Part D Plans - Accendo (S5644), and Community CCRx (S5803, S5825).

We appreciate the opportunity to review and provide additional comments regarding the proposed standard Medication Review and Summary document. We support the utilization of a standard format for the Medication Therapy Management Program (MTMP) Comprehensive Medication Review (CMR). This will ensure that the beneficiaries participating in the MTMP will have the information they need to better understand their medication therapy and to assist in their conversations with their prescribers.

We would like to reiterate earlier our earlier comment to allow the plan flexibility in the formatting of the CMR as long as the CMS required fields are present. We request that plans have flexibility in terms of the content layout (e.g., landscape rather than portrait orientation, boxed text vs non-boxed text) and that CMS not require precise replication of the document.

It is difficult to provide a start and stop date for the medications, especially chronic medications. The beneficiary may have started the medication while participating in a different Part D plan or before being eligible for Part D. We would recommend that only those drugs that the member is currently taking be included in the CMR and that the start/stop dates be optional, if required at all. This information can be included in the proposed optional field when it is relevant to the conversation with the beneficiary.

Thank you for the opportunity to provde these comments

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Comment On: CMS-2011-0113-0001
Medication Therapy Management Program Improvements—Standardized Format. (CMS-10396)

Document: CMS-2011-0113-DRAFT-0017
WI

Submitter Information

Name: Barbara Reid
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Eau Claire, WI, 54701
Organization: UnitedHealthcare Medicare & Retirement

General Comment

Please see attached document for full comments.

Attachments

UHC Cmnts MTM CMR Std Format 7-29-11

Barbara Reid
WI080-1000
2725 Mall Drive
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Phone: 715-832-5235
Email: barbara_reid@uhc.com

To: Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development

Attention: CMS-10396 / OCN: 0938-NEW

From: Barbara Reid
Regulatory Affairs Consultant
UnitedHealthcare Medicare & Retirement
UnitedHealth Group

Date: July 29, 2011

Re: Medication Therapy Management Program Improvements—Standardized Format

We have reviewed the collection *Therapy Management Program Improvements—Standardized Format* in response to the notice published under the Paperwork Reduction Act in the May 31, 2011 Federal Register (76 FR 31338) and provide the attached comments.

These comments are provided on behalf of UnitedHealthcare Medicare & Retirement and other UnitedHealth Group affiliates, including UnitedHealthcare Community and State, that manage Medicare Advantage and Part D business (collectively "United").

We greatly appreciate the opportunity to comment, and we look forward to continuing to work with CMS to develop successful products and services for Medicare beneficiaries. If you have any questions or concerns on our comments, please contact me at 715-832-5235 or via email at barbara_reid@uhc.com.

Comments Submitted by
UnitedHealthcare Medicare & Retirement/UnitedHealth Group
July 29, 2011

1. User/Beneficiary Testing
Beneficiary Cover Letter, Medication Action Plan, Personal Medication List

Issue: Standards for user testing have not been elucidated.

Recommendation: We recommend beneficiary testing of the standardized form by populating it with realistic data. User testing of a populated form will help identify any problem areas that may need improvement. In addition, we suggest user testing of the form in conjunction with the Plain Writing Act of 2010 to assure ease of use by beneficiaries.

2. Flexibility of Format
Beneficiary Cover Letter (BCL), Medication Action Plan (MAP), Personal Medication List (PML)

Issue: The current design of the BCL, MAP and PML does not include desired data elements that should be included in the materials (for example, see comments 4 and 6, below). In addition, the current formatting is not desirable as it significantly lengthens the document for the member (for example, see comment 4, below).

Recommendation: We recommend allowing a degree of flexibility in the design and format of the documents to meet each plan's needs.

3. Health Literacy Standards – Reading Level
Beneficiary Cover Letter (BCL)

Issue: The reading level of the BCL is at the 10th grade level. It should be at the 6th grade level as stipulated in the Plain Writing Act of 2010.

Recommendation: We suggest revising the BCL to further simplify the language in order to meet health literacy standards and improve the readability of the document for the beneficiary.

4. Health Literacy Standards – Extraneous Language
Personal Medication List (PML)

Issue: The format of the PML is not user friendly; it contains extraneous language that obstructs the flow of the document for the reader. For example, the repeated headers result in extraneous text for the reader.

Recommendation: We recommend reformatting to list drug names in column form followed by columns containing the other key parameters (days supply, prescriber name, start/stop dates, etc). This would be easier for the member to read and allow for more information on one page. Please see the example immediately below.

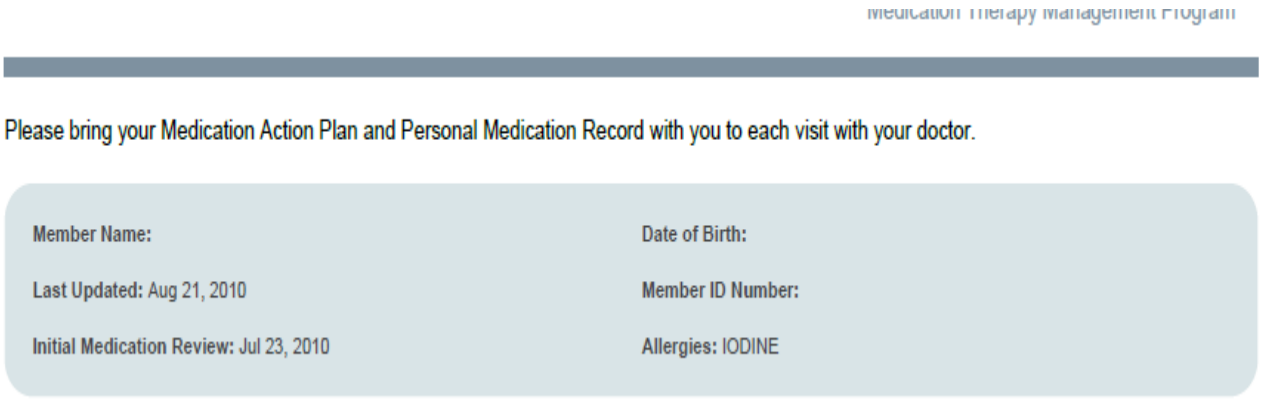
Medication	Quantity	Days Supply	Medication Fill Date	Name of Doctor on Prescription	Pharmacy
Aspirin 81mg Tablet	30	30	N/A	N/A	N/A
Colace 100mg Capsule	60	30	N/A	N/A	N/A
Mucinex 1200mg Extended-Release Tablet	60	30	N/A	N/A	N/A

5. Placement of Unique Member Identifiers

Medication Action Plan (MAP), Personal Medication List (PML)

Issue: The title of the MAP and PML require the inclusion of unique member identifiers (name, DOB, member ID) - this proposed format is not easy to read for the member.

Recommendation: We recommend creating a separate box/section at the top of the MAP/PML highlighting the key member identifiers (name, DOB, member ID number). Please see the example immediately below.



6. Associating Medications with the Clinical Issue

Medication Action Plan (MAP)

Issue: 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.

Recommendation: We 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 "None." Please see the example immediately below.

Medication: Simvastatin 5mg Tablet	What We Found: You are taking a medication called a statin to lower your cholesterol. It is important to check your liver regularly when taking a statin. Liver problems can increase your risk for side effects with this medication. Pharmacist recommendations: Talk to your doctor about checking your liver regularly. Your doctor may want to order a blood test to see how well your liver is working.

7. Medication Use Start Date

Medication Action Plan (MAP)

Issue: The "Date I started using it" field needs further clarification from CMS on how the data is gathered or should be revised. Adherence-related issues that are identified using medication possession ratio or percentage of days covered rely on prescription fill dates from claims. By using a member-reported date of use, this may contradict adherence-related issues identified and cause confusion for both the member and provider. There is also a high potential for inaccuracy and misreporting due to a member's ability to recall when medications were started.

Recommendation: We recommend changing this field to "Date I filled the medication" and using the prescription fill date from claims to populate it.

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Document: CMS-2011-0113-DRAFT-0018
DC

Submitter Information

Address:
DC, 20004

General Comment

See attached file(s)

Attachments

FinalAHIPCmnts_MTM CMR ActionPlanSum_8-1-11

America's Health Insurance Plans

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August 1, 2011

Centers for Medicare & Medicaid Services
Office of Strategic Operations and Regulatory Affairs,
Division of Regulations Development
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-10396

Dear Sir or Madam:

I am writing on behalf of America's Health Insurance Plans (AHIP) in response to the notice under the Paperwork Reduction Act concerning the "Medication Therapy Management Program Improvements—Standardized Format" that was published in the Federal Register (76 FR 31338) by the Centers for Medicare & Medicaid Services on May 31, 2011. AHIP is the national trade association representing the health insurance industry. Our member companies provide health care coverage to more than 200 million Americans. This draft is of significant interest to AHIP's member organizations, many of which participate in the Medicare Part D Prescription Drug Benefit (Part D) program.

We appreciate that during development of the proposed standardized format CMS provided an opportunity for comment and that the agency has taken into account the issues and recommendations that were submitted. We hope that the comments below will assist CMS in further refining the draft format.

GENERAL COMMENTS

- **Streamlining Draft Standardized Format.** Through longstanding experience communicating with beneficiaries on these topics, Part D sponsors have developed member materials that they have found to be both informative and user-friendly. CMS has acknowledged the value of existing materials by, as explained in the Supporting Statement, working to develop a draft format that is intended to be consistent with forms currently in use under sponsor Medication Therapy Management (MTM) programs. Accordingly, as discussed in our previous comments, we urge CMS to standardize the elements that must be provided to beneficiaries in the Medication Action Plan and Personal Medication List but provide flexibility for Part D sponsors to utilize their own

formats. This approach would ensure consistency in the information provided to Part D plan members, while taking advantage of sponsor experience to date and providing opportunities for further innovation. It would also mitigate plan sponsor investments associated with meeting the new CMS requirements by avoiding the need for significant systems redesign to accommodate a standardized format.

- **Burden Estimates.** On page 7 of the Supporting Statement, CMS estimates that the use of the standardized format will add 5 minutes to each Comprehensive Medication Review (CMR). However, it is our understanding that plan sponsors will need to manually populate some of the fields proposed and the inability to auto-populate these fields will substantially increase the time required to generate these materials for beneficiaries. For example, if CMS expects that plan sponsors will complete the "Why I use it" block in the Personal Medication List based upon information from the beneficiary's medical record, it is likely that this information would need to be modified to eliminate technical terminology and utilize language that is beneficiary-friendly. We recommend that CMS review and increase the burden estimate to reflect this circumstance.

SPECIFIC COMMENTS

Personal Medication List

- **Length and Format of Personal Medication List.** We continue to be concerned that the Personal Medication List format will result in a document that is too long and could be confusing and intimidating for beneficiaries. For example, the repeated headers complicate navigation of the document for the reader and are likely to be distracting rather than helpful. In addition, we believe the portrait layout of the document will result in an extremely bulky list. The document should be streamlined for ease of use (e.g., by permitting a chart layout), and the agency should allow sponsors to utilize either a portrait or a landscape layout, which we believe could accommodate information on a larger number of drugs on a single page. We believe that these changes will encourage beneficiaries to utilize the document as intended (e.g., to keep a record of their prescription over-the-counter medications, vitamins, etc).

- **Start/Stop Dates.** The introductory paragraph directs beneficiaries to "Use blank rows to add new medications and fill in the dates you started using them" and to "Cross out medications when you no longer use them and fill in the dates you stopped using them." It is our understanding that, in some cases, it can be difficult for a beneficiary to recall this information, specifically the start date. Consequently, if CMS' intent is to require plans sponsors to request this information during the CMR, this task could require a

significant amount of time and distract from other important topics that should be discussed. In addition, if the information is not supplied by the beneficiary, it could be difficult for a sponsor to confirm independently, particularly if the drug was started and or stopped during a period when the beneficiary was not enrolled in a plan offered by the sponsor. This is particularly problematic because we understand that many of the beneficiaries undergoing these reviews may be on eight or more medications. AHIP recommends that CMS issue instructions to accompany the Personal Medication List that explain that the licensed pharmacist or other qualified provider conducting the CMR is not responsible for completing these fields but should encourage the beneficiary to complete them.

We have appreciated the opportunity to comment. Please contact me if additional information would be helpful or if you have questions about the issues we have raised. I can be reached at (202) 778-3209 or cschaller@ahip.org.

Sincerely,

Candace Schaller
Senior Vice President, Federal Programs

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Medication Therapy Management Program Improvements—Standardized Format. (CMS-10396)

Document: CMS-2011-0113-DRAFT-0019
CA

Submitter Information

Name: Lorilyn Rosales-Menzel
Address:
Oakland, CA, 94612
Organization: Kaiser Foundation Health Plan, Inc.

General Comment

Please see the attached comments of Kaiser Foundation Health Plan, Inc. on the draft Standardized Format for Medicare Part D Medication Therapy Management Program

Attachments

LEGAL_DOCS-#589093-v7-Kaiser_Permanente_Comments_to_MTMP_Standardized_Format

COMMENTS OF KAISER FOUNDATION HEALTH PLAN, INC.

On Draft Standardized Format for Medicare Part D Medication Therapy Management Program

August 1, 2011

Kaiser Foundation Health Plan, Inc. and its subsidiary Health Plans ("Kaiser" or "Kaiser Permanente"), all of which are either Medicare Advantage organizations or Medicare Cost contractors pursuant to Section 1876 of the Social Security Act, appreciate the opportunity to comment upon the draft Standardized Format for the Medicare Part D Medication Therapy Management Program (CMS-10396; OMB# 0938-NEW) published in the May 3, 2011 Federal Register. Kaiser's comments are set forth below. If readers of these comments have any questions or seek further information, they may contact the following Kaiser attorney: Lorilyn Rosales-Menzel (lorilyn.m.rosales-menzel@kp.org, 510-271-6310).

Comments to the draft Standardized Format

Beneficiary Cover Letter

Approximately 40% of Medicare beneficiaries read at or below the 5th grade reading level. The language used in the draft Beneficiary Cover Letter, however, exceeds this reading level. The current draft of the Letter is written at a 10.2 school grade level according to the Flesch-Kincaid Grade Level Test. This reading level is not member-friendly and would likely lead to frustration for the average Medicare beneficiary. As such, Kaiser suggests that the Beneficiary Cover Letter be rewritten at a 5th grade reading level so that Medicare members are better able to comprehend the relevant text.

In the opening paragraph of the Beneficiary Cover Letter the second sentence reads "The MTM program helps people with Medicare use their medications safely". The Letter should be clear that the MTM program is only for those Medicare beneficiaries that qualify (i.e. meet the eligibility criteria in the program's MTM description) to participate. It is very common for Medicare beneficiaries with Part D coverage to request MTM services for their spouse when in fact their spouse does not qualify for participation in the MTM program. As such, Kaiser suggests the above sentence be revised as follows: "The MTM program helps *eligible* people with Medicare use their medications safely."

The second paragraph of the Beneficiary Cover Letter states that the Medication Action Plan has "steps you should take…." Although it is the Part D plan sponsor's goal to assist members in following their treatment plans and resolving their health issues, the Part D plan sponsor does not seek to cause the members anxiety or worry. The phrase "you should take" implies that the burden of following the treatment plan and achieving the desired health care goals falls solely on the member. Since the Part D plan sponsor

will work collaboratively with the member, we suggest that the word "should" be omitted and the sentence be revised as follows: "The Medication Action Plan has steps [*I/We recommend]* you ~~should~~ take to help you get the most benefit from your medications." Kaiser believes that MTM program participants will respond more favorably to the more collaborative tone of the suggested revised statement ("steps I/We recommend you take") and thus be more likely to follow the steps in the Action Plan as compared to the proposed directive tone of the existing text ("steps you should take").

There may be situations wherein no new Medication Action Plan is necessary for a MTM program participant. Such situations could occur if no changes have been made to the member's medications since their prior comprehensive medication review (CMR). This could also occur in cases wherein members that received a previous CMR performed recommended actions discussed in the prior CMR and thus corrected the issues or problems previously identified in the prior CMR. In sum, if a beneficiary is stable, with no identified opportunities or recommended actions, and currently has an appropriate Medication Action Plan in place, there is no need for the issuance of a new Medication Action Plan. In situations in which a new Medication Action Plan is not needed, the Personal Medication List would still be provided. Kaiser seeks confirmation from CMS that it is permissible to omit the provision of a new (and duplicative) Medication Action Plan in situations where it is not applicable or necessary for a particular member. In order to reflect this type of situation, Kaiser suggests the revision of the second paragraph of the beneficiary cover letter:

On <*insert date of service*>, <*we talked/you talked with* _____> about your health and medications you're taking. Attached to this letter are a Medication Action Plan and a Personal Medication List. [*Delete prior sentence and insert the following if appropriate*: Attached to this letter is a Personal Medication List. Our talk showed that your last Medication Action Plan is still current and addresses your current health status. Please refer to your existing Medication Action Plan as necessary.] The Medication Action Plan has steps [*I/We recommend]* you ~~should~~ take to help you get the most benefit from your medications. The Personal Medication List will help you keep track of your medications and how to take them the best way.

If, however, the omission of a new Medication Action Plan is not permissible, Kaiser suggests that in these limited circumstances [in which no new Medication Action Plan is needed/in which a new Medication Action Plan would be redundant] CMS permit Part D plan sponsors to complete the top portion of the new (and duplicative) Medication Action Plan that includes the member's name as well as the contact information and date prepared while noting in the section entitled "What we talked about and what I need to do:" the following statement: "No new action items identified; continue as discussed on [insert original date of service] and [date of most recent CMR]." This option would alleviate duplicative Medication Action Plans for members, facilitate efficiency for the Part D plan sponsors, and provide documentation that a CMR took place.

Medication Action Plan

In the current draft of the Medication Action Plan there are two separate boxes for the items "What we talked about" and "What I need to do". Kaiser suggests that these boxes be consolidated as this information is often duplicative in most situations. Thus, "What we talked about" and "What I need to do" would be consolidated into one single box that addresses both items. An example of this suggestion is detailed below.

Example scenario: What we talked about: having blood work done
What I need to do: go to the lab for blood work

The responses to the items "What we talked about" and "What I need to do" are so similar in nature that providing the member with a single response would be simpler, less time-consuming for the Part D plan sponsor, and easier for the member to review.

Recommended combined box example for above scenario:
What we talked about and what I need to do: go to lab for blood work

Kaiser also recommends that the Medication Action Plan should be formatted with one row for each item, instead of stacked columns. This format would more easily allow Part D plan sponsors to develop an automated computerized format with individual rows for each item.

Recommended format:

What we talked about and what I need to do: **<** *Insert description of topic >*
What I did and when I did it: **<** *Leave blank for patient's notes >*
Additional Information: *<Free-form text box for additional notes>*

Personal Medication List

The proposed draft of the Personal Medication List discusses each medication a member is taking separately from the others. This format is not conducive to easy review and understanding by the member. Rather, it would be easier for members to use/read the Personal Medication List if formatted with a row for each medication with respective columns for the required information. Each row would contain an individual medication as displayed in the example below.

Medication	Directions (how I use it)	Reason for use (why I use it)	Prescriber	Add'l info
Drug 1	Take 1 tablet in the morning	Blood pressure	Dr. John Smith	
Drug 2	Take 1 capsule 2 times a day	Diabetes	Dr. John Smith	
Drug 3	Take 1 tablet in the evening	Cholesterol	Dr. Joan Simpson	

In addition to the suggested format, Kaiser recommends that "Date I started using it" and "Date I stopped using it" not be included on the Personal Medication List. This recommendation is based on several reasons. First, such information is very difficult to determine in most instances and poses significant challenges for plan sponsors in terms of automating the data pull for the creation of the Personalized Medication List. Researching the start date for each medication of a member will significantly lengthen the amount of time needed to complete a CMR (well beyond the additional 5 minutes estimated by CMS). For Part D plan sponsors with an electronic medical record, such as Kaiser, this added research time is due to the fact that an automated data pull for the start date would result in the most recent date in which the member's prescription was refilled or rewritten. The original start date of the medication would not be auto-populated; thus, the original start date of the medication would need to be manually researched and entered into the Medication List. Moreover, despite the fact that some Part D plan sponsors have an electronic medical record for their members, the data needed to complete the suggested fields in the Personal Medication List is not always available electronically. New members of the Part D plan may be taking medications that were started many years ago and frequently members do not recall the exact date they started taking their various medications.

Second, the start date is only clinically significant for certain medications (i.e. Plavix); such information can be included in the "Additional Information" column if needed. Also, if the patient does not know the date he or she started taking a medication, the pharmacist will not enter a date in this field. This blank field may be confusing to the member.

Third, the stop date is generally not necessary as the Personal Medication List is designed to be a regularly updated document. The "end date" would not be pertinent for the chronic or maintenance medications that most of the elderly Medicare members take and are not anticipated to have an effective "end date". In other words, the field for the "end date" would be blank more often than not since the "end date" would only apply to those short-term (acute) therapies such as antibiotics where the prescription is for a finite number of days. In sum, Kaiser believes both the "start date" and "end date" fields should be omitted. This recommendation is based on the high probability for blank fields in either the "start date" or "end date" or both, these blanks may be confusing and/or misleading to members, these fields are not clinically significant for members in most instances, and these fields are difficult for members and Part D plan sponsors to obtain and document. Furthermore, any relevant "start date" and/or "end date" information can be captured in the "Additional Information" column as necessary.

If, however, the complete omission of the “start date” and “end date” fields is not permissible, Kaiser proposes that a check box be utilized to assist in capture of relevant data. More specifically, Kaiser suggests that a checkbox with the following wording: "medication started within the last 3 months" be included. This checkbox would provide the member and the Part D plan sponsor with relevant information with respect to more recent versus more long-term medications while not adding significant research and time burdens on the Part D plan sponsors with respect to “start dates” and “end dates”.

Resource Allocation

Kaiser disagrees with the CMS estimate of the resource allocation for the completion of the proposed Standardized Format. According to the Supporting Statement for Paperwork Reduction Act Submissions: Medication Therapy Management Program Improvements, Section B.12 (Burden Estimates), CMS estimates that the use of the proposed Standardized Format will add only an additional five (5) minutes to the time to conduct the annual interactive CMR and complete the written document for the member. Kaiser estimates that the completion of the Standard Form in its proposed form will take approximately thirty (30) minutes.

Currently, Kaiser estimates the average time for preparing the medication action plan and summary document is approximately fifteen (15) minutes (based on the use of a letter template in Kaiser’s electronic health record system wherein the active medication table is pulled into the template letter). With the proposed draft Standard Format, the Kaiser MTM Program staff would need to manually complete each of the fields of the Standard Format by free text typing as the required fields would not be populated electronically. This manual process would involve increased use of staff time to complete the CMR (including action plan and summary) especially if members have numerous medications.

We estimate that in addition to the 15 minutes that it currently takes to complete a medication action plan and summary, the Standard Format would add an additional 15 minutes of production time for researching the required information and populating the fields. This added research time is particularly relevant to the currently proposed “start date” and “end date” fields in the Medication List. Also, this is relevant to the need for Part D plan sponsors to provide the information in the Standard Format in language that is member-friendly and non-clinical if possible (e.g. using the term “high blood pressure” rather than “hypertension”). This “member friendly” language use is a manual process that cannot be accomplished by an automated process. In sum, the proposed draft of the Standardized Format will result in significant time and resource allocations for plan sponsors above and beyond CMS’ estimate. The proposed draft is also less-efficient for administration of the annual CMR and medication action plan.

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Medication Therapy Management Program Improvements—Standardized Format. (CMS-10396)

Comment On: CMS-2011-0113-0001
Medication Therapy Management Program Improvements—Standardized Format. (CMS-10396)

Document: CMS-2011-0113-DRAFT-0020
DC

Submitter Information

Address:
DC, 20004

General Comment

See attached file(s)

Attachments

Paperwork reduction MTMP format_final

PCMA
PHARMACEUTICAL CARE MANAGEMENT ASSOCIATION

August 1, 2011

Michelle Shortt
Director, Regulations Development Group
Office of Strategic Operations and Regulatory Affairs
Attention: CMS-10396/OMB 0938-NEW
Centers for Medicare and Medicaid Services
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Re: Medication Therapy Management Program Improvements – Standardized Format (CMS-10396/OMB 0938-NEW)

Dear Ms. Shortt:

The Pharmaceutical Care Management Association (PCMA) appreciates the opportunity to submit comments in response to the new collection of information: Medication Therapy Management Program Improvements – Standardized Format. PCMA is the national association representing America's pharmacy benefit managers (PBMs), which administer prescription drug plans for more than 210 million Americans with health coverage through Fortune 500 companies, health insurers, labor unions, and Medicare.

PCMA's members administer the Medicare Part D prescription drug benefit for millions of Americans and we appreciate the opportunity to provide CMS input on the many important Part D implementation issues throughout the year.

PCMA members are very supportive of medication therapy management programs (MTMPs). We believe these programs help improve outcomes for Medicare beneficiaries who take multiple prescription drugs. We believe that the recommendations below would improve the standardized format for the Personal Medication List that CMS submitted to the Office of Management and Budget (OMB) for review.

While we believe that knowing all of the drugs that a beneficiary has taken or is taking may, in some instances, be useful, we are concerned that obtaining all of the proposed information for the Personal Medication List may be a time-intensive exercise that would occupy much of the pharmacist's MTMP session with the beneficiary to the detriment of clinical counseling.

Medication Start Dates: It is the experience of PCMA members that patients generally do not know when they started a drug and that when they provide information about their start dates, the information frequently is inaccurate. In cases where the beneficiary recently has joined the Part D Plan and was already taking a medication, the Part D Plan would not know the original start date. This also could be true in cases where the patient

has a hiatus in therapy. The time that it would take to attempt to obtain this often unreliable information from the patient would be better spent providing clinical counseling to the beneficiary.

***PCMA Recommendation**: PCMA recommends that the field "Date I started using it [the medication]" should be deleted.*

Format: PCMA believes that CMS should permit the Personal Medication List to be displayed in a "landscape" format. We believe that, in many cases, a "landscape" format would be easier for patients to read and understand. Allowing Plan Sponsors the flexibility of using either the portrait or landscape format would provide for a more seamless transition to the new standard format based on their existing data systems, while still capturing all of the required information on the standardized form.

***PCMA Recommendation**: PCMA recommends that the Personal Medication List be permitted to be formatted in a landscape orientation.*

Thank you for the opportunity to provide feedback on the standardized format for the Personal Medication List. As always, we appreciate your consideration of our comments and look forward to continuing to work with CMS to ensure the most successful Part D program possible.

Sincerely,

Michelle Galvanek
Vice President, Regulatory Affairs

PUBLIC SUBMISSION

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Medication Therapy Management Program Improvements—Standardized Format. (CMS-10396)

Comment On: CMS-2011-0113-0001
Medication Therapy Management Program Improvements—Standardized Format. (CMS-10396)

Document: CMS-2011-0113-DRAFT-0021
DC

Submitter Information

Name: Anna Schwamlein Howard
Address:
Washington, DC, 20049
Organization: AARP

General Comment

See attached file(s)

Attachments

AARP Comments on MTM Final 8-1-11

August 1, 2011

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Department
Attention: Document Identifier/OMB Control Number
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medication Therapy Management Program Improvements – Standardized Format; Document Identifier Form Number CMS-10396 (OCN: 0938-New) 76 Fed. Reg. 31331 (May 31, 2011)

AARP is pleased to comment on the request for information on CMS' Medication Therapy Management Program Improvements – Standardized Format. AARP supports the value of medication therapy management (MTM) services in helping to ensure safe and appropriate use of prescription drugs by Medicare Part D enrollees.

The following comments pertain to each of the three standardized format documents.

Cover Letter: This is designed to be sent to the MTM enrollee following their participation in a comprehensive medication review ("CMR") (either telephonic, or face-to-face). To enhance both understanding of and appreciation for MTM, as well to provide consideration for lower-literacy recipients, we recommend:

1. The opening reference to the "MTM program" should state that it is a free benefit for Medicare Part D enrollees "such as yourself." There should also be a reference that "your XYZ plan offers MTM because we want to help you get the most benefit from your medicines. We also want to work with you to prevent and resolve any problems you may have with your medicines."
2. Reinforce the patient's role in "helping to get the most from your medicines. One of the most important steps you took towards this mutual goal was in meeting (in person/by phone) with XYZ-MTM provider on XXX (date). He/she talked with you about all of your medicines – even ones that may not be covered by Medicare Part D."
3. Remind the patient of what was promised at that (CMR) meeting – that they would soon receive a Medication Action Plan and Personal Medication List.

4. Add bulleted present-tense Action Steps to: (1) review and/or keep these documents up-to-date; (2) review them with family members and caregivers; and (3) take them to medical appointments, including the hospital, to share with health care providers.
5. The closing paragraph should also be bulleted, with clear Action Steps. Box the text with the key MTM provider's contact information.
6. The patient's principal prescriber should be copied on the letter.

Medication Action Plan Form:

1. Prioritize, and list in present-tense Action Steps, what the patient should do with this form.
2. Patients organize their medical "to-do" lists around their specific disease condition/body part. Thus, the "What we Talked About" field should be re-named to reflect this reality.
3. Eliminate the "What I need to Do" field, and incorporate it into the above field.
4. The "What I did and when I did it" is very confusing. Perhaps there could be pre-formulated actions (e.g., eat before taking medicine; remain upright after taking medicine; avoid coffee and other caffeinated drinks; avoid alcohol) with check-boxes so that the patient does not have to read possibly lengthy narrative statements.
5. All medications being taken for one particular condition should be grouped together on the form.
6. Add a text field, "Problems I am having with this medicine." This would reinforce the patient's role in MTM. (Include a related Action Step, as necessary.)
7. Put in boxed text the reminder, "If you have any questions" and include the contact information for the MTM provider
8. All prescribers treating the patient should be sent a copy of this form for their records.

Personal Medication List:

1. Combining this list with the Medication Action Form will make the patient's/caregiver's responsibility in MTM much simpler.
2. All medications used for a particular condition should be grouped together on the form.
3. Utilize a landscape format, which is more typical for PMLs.
4. The instruction about "use blank rows" could be very confusing.
5. At the top of the form, prioritize, and list in present-tense, specific Action Steps.
6. Add a field to reflect if any monitoring tests are required, plus frequency of such tests.
7. Consider dedicated text boxes to list (1) over-the-counter drugs, and (2) dietary supplements. Without dedicated boxes, they may be overlooked completely.
8. For the annual "Medicare & You" handbook, use the personal medication list as a insert that can be easily removed by the consumer. Regardless if Medicare beneficiaries are Part D enrollees and MTM-eligible, they can all benefit from keeping a PML.

Regardless of the specific form, the new standardized content should be offered to patients in hard copy, or electronic versions, and/or via an "app." (These multiple delivery modes could be phased in, if necessary.) Other stakeholders have raised the suggestion that the MTM forms should be totally integrated with electronic health records; doing so could support federal HHS' "meaningful use" goals. While ensuring the utility of these MTM communication tools is the focus of this Information Collection activity, to advance the broader goals of Medicare Part D, it is important that these tools do not inadvertently create "work-arounds" for the clinician, or for the patient.

AARP appreciates the dedication of CMS staff to enhancing medication therapy management services under Part D, and the frequent opportunity for stakeholder input. If you have questions, please feel free to contact Anna Schwamlein Howard on our Government Affairs staff at (202) 434-3770.

Sincerely,

David Certner
Legislative Counsel & Legislative Policy Director
Government Affairs

PUBLIC SUBMISSION

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Comment On: CMS-2011-0113-0001
Medication Therapy Management Program Improvements—Standardized Format. (CMS-10396)

Document: CMS-2011-0113-DRAFT-0022
DC

Submitter Information

Name: Hilary Dalin
Address:
Washington, DC, 20036
Organization: National Council on Aging

General Comment

Attached please find the comments of the National Council on Aging regarding the Medicare Part D template Medication Therapty Management Program standardized format.

Attachments

MTMP Standardized Format Comment_8.1.11

NCOA
NATIONAL COUNCIL ON AGING

Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: Medication Therapy Management Program Standardized Format

Dear Sir or Madam,

We thank you for the opportunity to comment on the Part D medication therapy management standardized notification format.

The National Council on Aging (NCOA) is a nonprofit service and advocacy organization that serves as a national voice for older Americans and the community organizations that serve them. The National Center for Benefits Outreach and Enrollment is housed at the National Council on Aging. The Center helps organizations enroll seniors and younger adults with disabilities with limited means into the benefits programs for which they are eligible so that they can remain healthy and improve the quality of their lives.

We have reviewed the standardized format for confirming with Medicare Part D plan members that they have received medication therapy management counseling. When appropriately used, medication therapy management can be a tremendously valuable tool to enable Part D plans and their members targeted for medication therapy management encounters—those with multiple high-risk chronic conditions and high drug utilization— and the pharmacists with whom they interact to collaboratively enhance each member's health status.

We offer our comments from this perspective.

1. We are in full agreement with CMS that a standardized format will best enable participating plan members to understand and benefit from the consultation. It will also assure that pharmacists performing the management service adhere to a protocol designed to achieve positive outcomes for plan members.

2. We believe the format is easy to navigate and understand. This document should be subject to the language access standards applicable to Part D plan communications with members—translated into primary languages other than English spoken by 5 percent or more of the population in each plan's service area.

3. We urge you to include in the Action Plan a check-off list of the most common topics the pharmacist might discuss with the plan member. Such a check-off list would encourage a thorough means of recording the topics discussed, avoiding the risk of cryptic or incomplete

notations by the party completing the blanks on the form. These might include items such as 'adverse events', 'use of non-prescription medications or supplements', 'health status', 'medication history', 'disease management programs', etc.

4. Because medication therapy management 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, medication therapy management should not be used to switch a participant to a different drug in the absence of a consultation between the prescriber and patient.

5. The development of the Action Plan offers a unique opportunity for pharmacists to offer objective, person-centered education to participating plan members about their rights regarding formulary and tiering exceptions. We recommend that you to add these items to the standard for medication therapy management. Likewise, these encounters with pharmacists could be used to explain any utilization management protocols applicable to the participating member's drug regimen and this topic too should be added to the standard format so pharmacists are prompted to explore these matters with members as appropriate.

6. In the directions contained in bullets above the Action Plan fields, we suggest adding to the third bullet that plan members *may* but do not need to complete the "what I did" boxes, and do not need to submit the form to anyone; rather the form is for their personal education and use.

7. The third bullet explaining the personalized medication list should be given more emphasis – that this document should be shared with prescribers and should form the basis for meaningful interactive discussions between plan members and their prescribers about prescribed medications in the context of overall health status.

8. It may be challenging for some medication therapy management participants to be able to add to the medication list, or to bring the Action Plan with them to the hospital or ER. The text should emphasize that the list is intended as a helpful tool, not a mandatory exercise for participants.

   If the pharmacist performing the service is affiliated with the pharmacy where the member fills prescriptions, encounters to fill new prescriptions might be viewed as a prompt to the pharmacy to add the information to the individual's medication list. Similarly, in between therapy management consultations, plans might use new drug claims, including those which indicate a hospital stay or ER visit, as opportunities to suggest that plan members and prescribers review drug regimens.

The National Council on Aging appreciates this opportunity to assist you in developing a revised point-of-sale notice of Part D prescription denials. If you have questions or would like to discuss this

comment, please contact Hilary Dalin, Director, Benefits Access Policy and Programs, Hilary.dalin@ncoa.org.

Yours,

Howard Bedlin
VP, Public Policy and Advocacy

Nora Dowd Eisenhower
VP, Benefits Access

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Comment On: CMS-2011-0113-0001
Medication Therapy Management Program Improvements—Standardized Format. (CMS-10396)

Document: CMS-2011-0113-DRAFT-0023
VA

Submitter Information

Name: Rebecca Snead
Address:
Richmond, VA, 23235
Organization: National Alliance of State Pharmacy Associations

General Comment

See attached file(s)

Attachments

NASPA Comments MTM standard format

National Alliance of State Pharmacy Associations
2530 Professional Road, Suite. 202, Richmond, VA 23235
Phone: (804) 285-4431 Fax: (804) 285-4227 www.naspa.us

[**Submitted electronically via http://www.regulations.gov**]

August 1, 2011

CMS
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development,
Attention: CMS-10147, CMS-10396 and CMS-R-246
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-10396 Comments regarding MTM standardized format

Dear Sir or Madam:

The National Alliance of State Pharmacy Associations (NASPA) promotes leadership, sharing, learning, and policy exchange among pharmacy leaders nationwide, and provides education and advocacy to support pharmacists, patients, and communities working together to improve public health. NASPA was founded in 1927 as the National Council of State Pharmacy Association Executives (NCSPAE).

We welcome this opportunity to comment on the Agency Information Collections Activities regarding the Medication Therapy Management Program Improvements – Standardized Format.

Medication Therapy Management Program Improvements – Standardized Format
We are supportive adding standardization to information patients receive with medication therapy management services provided under Medicare Part D and was pleased CMS sought input from stakeholders and appreciate the revisions that have been made since first drafted. The Affordable Care Act (ACA) under Section 10328 specifies that the Secretary, in consultation with relevant stakeholders, develop a standardized **format** for the action plan and written or printed summary to the beneficiary. We would assert this implies data elements and order of presentation not necessarily a prescribed **form.** We would suggest restricting it to **prescribed form (size of paper; orientation; boxes)** is contrary to the shift towards an electronically, connected health care system. It should be able to be distributed to the patient via their communication method of choice -in person, via fax, mail, email, or through their PHR. We envision a future where providers could through a mobile application continually update the action plan and personalized medication list with each interaction. This envisioned future does not fit with the rigidity of a particular form and is counterintuitive to where we all believe healthcare is going. In addition, we recommend that data requirements for MTM electronic transactions be incorporated into these documents. This would assure completion of documentation for the patient is driven off existing electronic data elements so that rekeying will not be necessary. This recommendation is supported through American National Standards Institute (ANSI) Standard Development Organizations including National Council for Prescription Drug Programs(NCPDP), Accredited Standards Committee (ASC X12), and Health Level Seven (HL7) processes to assure MTM electronic standard transactions are developed.

Draft Beneficiary Letter

We feel the revised draft beneficiary letter is much more streamlined and beneficial therefore we would request a few minor revisions be considered. In addition, as mentioned above, we would seek clarification as long as the beneficiary letter was sent to the patient through the means that met the patient preference to meet the requirements.

Suggested revisions to actual wording:

- Add "caregiver" language to letter – for example, "the personal medication list will help you or your caregiver keep track...."
- Add "pharmacist" to third paragraph, "available when you talk with your doctors, **pharmacist** and other health providers."
- Make sure the letter and all contact information references the **specific** healthcare provider that provided the MTM service.
- Suggest the Pers nal Medication List (PML) comes before the Medication Action Plan (MAP) in the communication as we believe it would be more beneficial for both the patient and for the physician, assuming that the patient will share the document during appointments, to view the personal medication list first followed by the medication action plan.

Medication Action Plan

In the header, modify bullets 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

Below the bullets, make the following revisions:
Have this information available when you talk with your doctors, **pharmacist**, and other healthcare providers.
Make sure the inserted "contact information" listed is the **specific** provider who provided MTM service.

Take into consideration that one conversation may have three to four action items, therefore it may not be necessary to repeat "what we talked about" multiple times I suggest that there be multiple bullets under "what I need to do".

At the end of the communication, remove additional information to allow free space for additional notes.

The footer section for plan/provider messaging, such as Medicare marketing statement, privacy statement, etc. only be required on the last page of document if the MAP contain multiple pages.

Personal Medication List

In the header, under the bullets:

Add a bullet, "Review list below for accuracy and completeness."
In the second bullet, delete everything in sentence after "no longer use them".

Add the following sentence between the first and second sentence of the paragraph under the bullets, "Have this list with you when you talk with your doctors, **pharmacist**, and other healthcare providers." In addition, the name and contact information should be of the person who compiled the list with the patient during their comprehensive medication review.

If we envision every patient having a medical home that they are attributed to, adding a section that would identify the patient's primary prescriber to include emergency contact information will be helpful for working towards this vision.

Have allergies and side effects as two separate data fields.
Clarify that you are requesting any medication and/or food allergies and ask "what was the reaction".

Once you get into the actual formatting of what is included on respective data elements of the PML and how they should be organized; I remain very concerned that we are creating a document that is not user friendly, easy to review, and will be cumbersome to create and update. I would omit anything but the most basic information such as medication name, when I take it, how I take it, and prescriber name.

Medications should be able to be "grouped" under a primary chronic disease header for ease of review and in helping understand which medications they are taking for each respective condition. As a result, this would replace the "why I use it field".

And the inclusion of start and stop dates is problematic, unrealistic and potentially confusing for the documenting pharmacist and the patient. Populating a start date based on claims data would be problematic due to changes in health plans both by patients or forced changes through plan designs/employers. These fields, particularly the stop date, seem likely to be applicable only to a very small number of the patient's medications, if any, and therefore are likely to be left blank. If the medication has been discontinued it should not appear on the PML.

The optional field titled, "Insert other title(s)" appears to have a great deal of variability in what this field may be used for and seem to go beyond the purpose of what a PML is intended to accomplish. Therefore, I would suggest omitting this respective field.

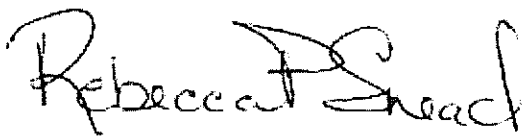
Remove additional information section at the end of the mediation list; it is not necessary.

The footer section for plan/provider messaging, such as Medicare marketing statement, privacy statement, etc. only is required on the last page of document if the PML contain multiple pages.

As you finalize regulations for MTM standardized format, NASPA respectfully urges you to consider these issues. We also urge CMS that prior to implementation, to test verbiage of the messages with beneficiaries to assure ease of use and health literacy appropriateness.

Thank you for the opportunity to comment.

Sincerely,



Rebecca P. Snead, RPh
Executive Vice President & CEO

PUBLIC SUBMISSION

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Medication Therapy Management Program Improvements—Standardized Format. (CMS-10396)

Document: CMS-2011-0113-DRAFT-0024
TN

Submitter Information

Name: Baeteena Black
Address:
Nashville, TN, 37219
Organization: Tennessee Pharmacists Association

General Comment

See attached file(s)

Attachments

TPA comments MTM standard format 8.1.11

VIA Electronic Submission to http://www.regulations.gov

August 1, 2011

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development
Attention: CMS–10396/OCN: 0938–New
Room C4–26–05
7500 Security Boulevard
Baltimore, Maryland 21244–1850

Re: CMS-10396; Information Collection: Medication Therapy Management Program Improvements—Standardized Format

Dear Sir or Madam:

Thank you for the opportunity to submit our comments on CMS's Information Collection regarding CMS's standardized format for documents associated with Part D Medication Therapy Management (MTM). As CMS considers finalizing the format for the Part D MTM documents, the National Community Pharmacists Association (NCPA) appreciates the opportunity to share our perspectives.

The National Community Pharmacists Association (NCPA®) represents the interests of America's community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together they represent a $93 billion health-care marketplace, have more than 315,000 employees including 62,400 pharmacists, and dispense over 41% of all retail prescriptions. NCPA members are the primary providers of drugs and pharmaceutical supplies to millions of Americans. Focusing on the Medicare Part D program, NCPA members are a primary access point for prescription medications for millions of Part D beneficiaries and NCPA members provide valuable MTM services to many of those Part D beneficiaries. According to a recent survey of NCPA members, in 2010, 67% of NCPA members offered MTM services to their patients.

Given the primary role that NCPA members play with regard to providing MTM services to Part D beneficiaries, we believe that it is of utmost importance that the standardized MTM forms be functional and concise. In order for patients to receive the maximum benefit from MTM services it is critical that CMS use standardized MTM forms that are as patient friendly as possible. While NCPA appreciates the changes that CMS has already adopted versus the format of the original draft MTM forms, NCPA urges CMS to adopt the additional following suggested improvements to CMS's proposed standardized MTM forms.

100 Daingerfield Road
Alexandria, VA 22314-2888
(703) 683-8200 PHONE
(703) 683-3619 FAX

Incorporating Data Requirements for MTM Electronic Transactions into the "Standardized Format for the Comprehensive Medication Review Action Plan and Summary"

NCPA recommends that data requirements for MTM electronic transactions be incorporated into the "Standardized Format for the Comprehensive Medication Review Action Plan and Summary". This would assure completion of the forms for the patient is driven off existing electronic data elements so that rekeying will not be necessary. This recommendation is supported through American National Standards Institute (ANSI) Standard Development Organizations including National Council for Prescription Drug Programs(NCPDP), Accredited Standards Committee (ASC X12), and Health Level Seven (HL7) processes to assure MTM electronic standard transactions are developed.

Improve the Clarity of the MTM Standardized Forms

Generally, NCPA is concerned that CMS' guidance on these standardized MTM forms is unclear on whether Part D plans or practitioners should be the ones to send out these documents to beneficiaries. Given this lack of clarity, NCPA is concerned that beneficiaries will be confused as to whom to go to for questions and answers and on what type of issues should be addressed by the Part D plans or the practitioner.

More specifically, NCPA believes that the three standardized MTM forms (the Beneficiary Cover Letter, Medication Action Plan and Personal Medication List), as drafted, still lack sufficient clarity in a number of places, which is likely to result in patient confusion. First, with regard to the Beneficiary Cover Letter, CMS has said that the plans have the option to customize the contact information to direct beneficiaries to either an individual practitioner or a corporate official. While NCPA has no objection to including the plan's contact information within the cover letter, NCPA believes that the letter header and the body of the letter should also make clear to the beneficiary the MTM provider's identity and contact information. The same is true for the headers and questions/concerns references within the Medication Action Plan and Personal Medication List forms. In each of these places on the forms, patients should be able to easily identify the contact information for the MTM provider, should they have questions or concerns. The MTM provider, not the plan, is the proper source for answers to patient questions about their medications and their Medication Action Plan.

Similarly, the Beneficiary Cover Letter still needs more precision in the second paragraph with regard to the phrase "we talked/you talked with _____ about your health and medications." Because CMS is allowing these cover letters to be sent by either the provider or a plan official, this phrase has the potential to be inaccurate. It should state the name of the MTM provider that reviewed the patient's medications, not the plan, regardless of whether the plan or the provider is sending the letter. This information should be repeated in the last paragraph of the cover letter, as well. As currently drafted, the last paragraph could be phrased to direct patients with questions to call either the MTM provider or the plan. As stated above, the MTM provider, not the plan, is the proper source to answer patient questions regarding the clinical aspects of MTM services.

NCPA believes that making the changes suggested above will add clarity to the forms and avoid potential patient confusion, which is likely to result from the proposed form language.

Add Flexibility to the MTM Personal Medication List

Along with increased clarity, NCPA also seeks greater flexibility in the structure of the Personal Medication List. NCPA remains concerned that MTM providers may not always have access to all of the information needed to complete the Personal Medication List, as it is currently worded.

First, NCPA is concerned that MTM providers may not always be able to obtain a patient's start and stop date for a medication. Accordingly, MTM providers should have some flexibility in how or whether they fill out that element. MTM providers may not always be able to obtain the "start/stop date" elements from the patient or the patient's prescriber.

Second, as to the stop date, NCPA believes that if a medication has been discontinued prior to the comprehensive medication review (CMR) that medication should not appear on the Personal Medication List. The Personal Medication List should only list those drugs, which the patient is currently taking. Accordingly, NCPA recommends that CMS remove the stop date field from the Personal Medication List, as this field would have to be manually completed at a subsequent time if and when a medication is actually discontinued.

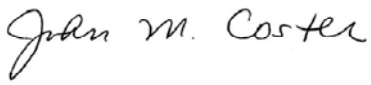
If the Personal Medication List does not contain enough flexibility, NCPA is concerned that MTM providers may be placed in a situation in which they are unable to obtain the requested information, and yet they may be penalized for the failure to report such information, through auditing or other oversight. In other words, if the standardization of the Personal Medication List is too stringent, MTM providers may lose reimbursement for a failure to report information, which is beyond their control. Accordingly, NCPA urges CMS to allow for some level of flexibility in the structure and/or reporting on the Personal Medication List, and to provide guidance regarding that flexibility.

Conclusion

In conclusion, NCPA and its members enthusiastically support CMS's efforts to streamline MTM services within Medicare Part D. However, we also urge CMS to incorporate electronic MTM data elements into the MTM standardized forms, to provide further clarification on the structure of the MTM standardized forms and to allow for sufficient flexibility in the structure of those forms. In order to be most effective, the standardized forms must be clear, concise and patient friendly.

NCPA appreciates the opportunity to comment on CMS' draft MTM standardized forms. Please do not hesitate to contact Chris Smith by email at chris.smith@ncpanet.org, or by telephone at (703) 600-1185, if you have any questions.

Sincerely,



John M. Coster, Ph.D., R.Ph.
Senior Vice President, Government Affairs
and Director, NCPA Advocacy Center

Tennessee Pharmacists Association

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Phone: 615/256.3023 Fax: 615/255.3528
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[**Submitted electronically via http://www.regulations.gov**]

August 1, 2011

CMS
Office of Strategic Operations and Regulatory Affairs
Division of Regulations Development,
Attention: CMS-10147, CMS-10396 and CMS-R-246
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-10396 Comments regarding MTM standardized format

Dear Sir or Madam:

The Tennessee Pharmacists Association (TPA), on behalf of pharmacists in all practice settings in Tennessee and the patients they serve, appreciates the opportunity to submit our comments on the Agency Information Collections Activities regarding the Medication Therapy Management Program Improvements – Standardized Format.

Medication Therapy Management Program Improvements – Standardized Format
We are supportive adding standardization to information patients receive with medication therapy management services provided under Medicare Part D and was pleased CMS sought input from stakeholders and appreciate the revisions that have been made since first drafted. The Affordable Care Act (ACA) under Section 10328 specifies that the Secretary, in consultation with relevant stakeholders, develop a standardized **format** for the action plan and written or printed summary to the beneficiary. We would assert this implies data elements and order of presentation not necessarily a prescribed **form.** We would suggest restricting it to **prescribed form (size of paper; orientation; boxes)** is contrary to the shift towards an electronically, connected health care system. It should be able to be distributed to the patient via their communication method of choice -in person, via fax, mail, email, or through their PHR. We envision a future where providers could through a mobile application continually update the action plan and personalized medication list with each interaction. This envisioned future does not fit with the rigidity of a particular form and is counterintuitive to where we all believe healthcare is going. In addition, we recommend that data requirements for MTM electronic transactions be incorporated into these documents. This would assure completion of documentation for the patient is driven off existing electronic data elements so that rekeying will not be necessary. This recommendation is supported through American National Standards Institute (ANSI) Standard Development Organizations including National Council for Prescription Drug Programs(NCPDP), Accredited Standards Committee (ASC X12), and Health Level Seven (HL7) processes to assure MTM electronic standard transactions are developed.

Draft Beneficiary Letter

We feel the revised draft beneficiary letter is much more streamlined and beneficial therefore we would request a few minor revisions be considered. In addition, as mentioned above, we would seek clarification as long as the beneficiary letter was sent to the patient through the means that met the patient preference to meet the requirements.

Suggested revisions to actual wording:

- Add "caregiver" language to letter – for example, "the personal medication list will help you or your caregiver keep track…."
- Add "pharmacist" to third paragraph, "available when you talk with your doctors, **pharmacist** and other health providers."
- Make sure the letter and all contact information references the **specific** healthcare provider that provided the MTM service.
- Suggest the Personal Medication List (PML) comes before the Medication Action Plan (MAP) in the communication as we believe it would be more beneficial for both the patient and for the physician, assuming that the patient will share the document during appointments, to view the personal medication list first followed by the medication action plan.
- Add "correctly" to the end of the last sentence of the first paragraph so that it reads "make sure that your medications are working *correctly*.

Medication Action Plan

In the header, modify bullets 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

Below the bullets, make the following revisions:

Have this information available when you talk with your doctors, **pharmacist**, and other healthcare providers.

Make sure the inserted "contact information" listed is the **specific** provider who provided MTM service.

Take into consideration that one conversation may have three to four action items, therefore it may not be necessary to repeat "what we talked about" multiple times I suggest that there be multiple bullets under "what I need to do".

At the end of the communication, remove additional information to allow free space for additional notes.

The footer section for plan/provider messaging, such as Medicare marketing statement, privacy statement, etc. only be required on the last page of document if the MAP contain multiple pages.

Personal Medication List

In the header, under the bullets:

Add a bullet, "Review list below for accuracy and completeness."
In the second bullet, delete everything in sentence after "no longer use them".

Add the following sentence between the first and second sentence of the paragraph under the bullets, "Have this list with you when you talk with your doctors, **pharmacist**, and other healthcare providers."

In addition, the name and contact information should be of the person who compiled the list with the patient during their comprehensive medication review.

If we envision every patient having a medical home that they are attributed to, adding a section that would identify the patient's primary prescriber to include emergency contact information will be helpful for working towards this vision.

Have allergies and side effects as two separate data fields.
Clarify that you are requesting any medication and/or food allergies and ask "what was the reaction".

Once you get into the actual formatting of what is included on respective data elements of the PML and how they should be organized; I remain very concerned that we are creating a document that is not user friendly, easy to review, and will be cumbersome to create and update. I would omit anything but the most basic information such as medication name, when I take it, how I take it, and prescriber name.

Medications should be able to be "grouped" under a primary chronic disease header for ease of review and in helping understand which medications they are taking for each respective condition. As a result, this would replace the "why I use it field".

And the inclusion of start and stop dates is problematic, unrealistic and potentially confusing for the documenting pharmacist and the patient. Populating a start date based on claims data would be problematic due to changes in health plans both by patients or forced changes through plan designs/employers. These fields, particularly the stop date, seem likely to be applicable only to a very small number of the patient's medications, if any, and therefore are likely to be left blank. If the medication has been discontinued it should not appear on the PML.

The optional field titled, "Insert other title(s)" appears to have a great deal of variability in what this field may be used for and seem to go beyond the purpose of what a PML is intended to accomplish. Therefore, I would suggest omitting this respective field.

Remove additional information section at the end of the mediation list; it is not necessary.

The footer section for plan/provider messaging, such as Medicare marketing statement, privacy statement, etc. only is required on the last page of document if the PML contain multiple pages.

As you finalize regulations for MTM standardized format, TPA respectfully urges you to consider these issues. We also urge CMS that prior to implementation, to test verbiage of the messages with beneficiaries to assure ease of use and health literacy appropriateness.

Thank you for the opportunity to comment.

Sincerely,

Baeteena M. Black

Baeteena M. Black, D.Ph.
Executive Director

PUBLIC SUBMISSION

As of: August 02, 2011
Received: August 01, 2011
Status: Draft
Category: Health Care Professional/Association - Pharmacist
Tracking No. 80ed33c5
Comments Due: August 01, 2011
Submission Type: Web

Docket: CMS-2011-0113
Medication Therapy Management Program Improvements—Standardized Format. (CMS-10396)

Comment On: CMS-2011-0113-0001
Medication Therapy Management Program Improvements—Standardized Format. (CMS-10396)

Document: CMS-2011-0113-DRAFT-0025

Submitter Information

Name: Ronna Hauser
Address:
Alexandria, 22314
Organization: National Community Pharmacists Association (NCPA)

General Comment

Attached please find comments submitted by the National Community Pharmacists Association (NCPA).

Attachments

110801 NCPA re CMS-10396 -Information Collection - MTM - Standardized Format

PUBLIC SUBMISSION

As of: August 02, 2011
Received: August 01, 2011
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Tracking No. 80ed351e
Comments Due: August 01, 2011
Submission Type: Web

Docket: CMS-2011-0113
Medication Therapy Management Program Improvements—Standardized Format. (CMS-10396)

Comment On: CMS-2011-0113-0001
Medication Therapy Management Program Improvements—Standardized Format. (CMS-10396)

Document: CMS-2011-0113-DRAFT-0026
DC

Submitter Information

Name: Marcie Bough
Address:
Washington, DC, 20037
Organization: American Pharmacists Association

General Comment

Please see attached comments from the American Pharmacists Association.

Attachments

APhA Comments to CMS on MTM Standardized Format for MAP 080111 Final

American Pharmacists Association®
Improving medication use. Advancing patient care.
APhA

August 1, 2011

Centers for Medicare and Medicaid Services
Office of Strategic Operations and Regulatory Affairs
Division of Regulatory Development
Attention: CMS-10396
Room C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

[Submitted online at: www.regulations.gov]

Re: Docket No. CMS–10396. CMS Information Collection Request: Medication Therapy Management Program Improvements – Standardized Format

Dear Sir/Madam:

The American Pharmacists Association (APhA) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed information collection request, *Medication Therapy Management Program Improvements— Standardized Format*, published May 31, 2011 (76 FR 31338). APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services. Our comments reflect the views of pharmacists practicing across the spectrum of health and patient care settings.

APhA greatly appreciates CMS' work in developing the proposed draft standardized format for the written summary and action plan as part of the comprehensive medication review in the Medicare Part D Medication Therapy Management (MTM) program: the Beneficiary Cover Letter, Medication Action Plan (MAP), and Personalized Medication List (PML). We also appreciate that CMS continues to seek input on the proposal to further build on previous information requests, an environmental scan, and literature reviews of formats currently in use within the industry for medication review summaries and/or action plans. We are pleased that CMS has made significant improvements in many respects compared to previous versions of the document.

We are also pleased that CMS indicates that with the proposed form, specific content must be tailored to the beneficiary and customized for the Part D sponsor or MTM program and that plan sponsors are encouraged to augment the standardized format by providing additional materials as needed to help

beneficiaries manage their healthcare needs. We encourage such information be include in a CMS developed plan/pharmacy/pharmacist instruction guide for the documents.

As indicated in our March 2011 comments to CMS on this issue, our comments build on member feedback and our experience with the *Medication Therapy Management in Pharmacy Practice: Core Elements of an MTM Service Model* (Version 2.0)[1] (Core Elements) developed with the National Association of Chain Drug Stores Foundation and supported by 7 other national pharmacy associations. As in our previous comments, APhA generally supports the overall direction and intent of the draft standardized template. To further improve the changes that have already been incorporated into the document, we recommend that CMS consider the following revisions/clarifications as the standardized template is finalized.

General Recommendations

- Develop a plan/pharmacy/pharmacist instructions document on how the standardized template is to be used. Clarification and intent language for the information that should populate a field should be included in such an instruction page. In addition, option for populating fields with standardized text versus free text should be included.
- Provide specifics on the format that CMS expects the patient to receive the document – exactly in the template format as presented by CMS or other options. Specifically, clarify if plans/pharmacies/vendors have flexibility in what the document looks like and how it prints out for the patient while including all fields as required by CMS.
- Provide specifics on the distribution options for how CMS expects the patient to receive the information, for example, via print copy or electronically but preferably in the format the patient prefers.
- Clarify that pharmacists can complete the documents in an electronic format.
- Clarify if there are space/character limits for the fields to be populated in the template.
- Ensure that data elements are consistent and compatible with pharmacy operating and software systems so that the templates can, to the extent possible, reduce errors and be auto-populated with information from a pharmacy operating system and/or documentation program. Such elements should be consistent with the pharmacy electronic health record functional profile for the patient.
- Indicate what flexibility, if any, plans and pharmacies have in integrating the form into existing software and printing systems. We have heard concerns from members about printing the in the exact format of the proposal with the heavy use of lines/boxes using their existing electronic documentation and computer systems.
- Clarify the timeline in which the document is to be distributed to the patient (i.e. at the end of the CMR session or afterwards once information is documented, verified, and/or if needed discussed with the prescriber.)
- Continue to evaluate the readability and literacy level of the document.

[1] APhA and National Association of Chain Drug Stores Foundation. Medication therapy management in practice: Core Elements of an MTM Service Model. Version 2.0 2008. Available at: http://www.pharmacist.com/AM/Template.cfm?Section=Resource_Library&CONTENTID=19013&TEMPLATE=/CM/ContentDisplay.cfm.

Beneficiary Cover Letter Recommendations

- Clarify the intended use of the "< Additional Space For Plan/Provider Use >" space, and indicate that it is not to be used for marketing messages or other sales information.
- Clarify that the text "< *we talked/you talked with* _____ >" is intended for the name of the pharmacist or other provider who provided the MTM service.

Medication Action Plan Recommendations

- Clarify that the "< *insert contact information, phone number, days/times, etc*. >" is intended for the pharmacist or other provider who provided the MTM services. Consider revising "< insert contact information…>" to say: "< insert provider name…>".
- Delete the text box "Additional Information: < *Free-form text box for additional notes* >" as any such information should be included in the previous action plan fields. Based on feedback from our members, we are concerned that this section may provide the patient with too much information and take away from the importance of the key items already listed in the document. Given that the purpose of the MAP is to list the highest priority items for the patient to focus on, removing this section may improve patient understanding of the MAP.
- Consider streamlining the document by combining the potentially overlapping fields of " What we talked about:" and "What I need to do:" into one field that says "What I need to do about _____".

Personal Medication List Recommendations

- Clarify that the text to populate "< *insert sources of information* >" should indicate the patient, pharmacist, physician, pharmacy records, caregiver, family member, etc. that provided the information to populate the list. Source of information is important to ensure that reconciliation of any conflicting information can occur.
- 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." or something similar.
- Include additional information as to who the PML information should be shared with so that the first sentence of the second paragraph includes text already included in the MAP document "Have this information available when you talk to your doctors and other health care providers" or something similar to "Share this list of medications with your caregiver(s) and have it available when talking with your doctor, pharmacist, or other health care provider."
- Clarify the text "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.
- Include in a proposed plan/pharmacy/pharmacist instruction document the type of information that should be populated in the "<*Insert other titles(s) >"* field.
- Clarify the text "< *Insert other titles(s) >*" by changing it to something similar to "< *Insert supplemental information: >*" or "< *Insert additional information: >*". The term "*titles*" may be confusing as to intend use of the field.
- Clarify that the "< *insert contact information, phone number, days/times, etc*. >" field is intended for the pharmacist or other provider who provided the MTM services.
- Delete the text box "Additional Information: < *Free-form text box for additional notes* >" as it is unnecessary for this document and could be confusing to the patient.
- Consider revising the "Date I started taking it" text to say something similar to "When I started using it:"

- Revise the "Prescriber" field to say "Prescriber and phone number" to ensure that the patient and health care providers have access to the appropriate prescriber name and contact information for that medication.
- Consider reformatting the PML to a landscape chart format to list by medication or potentially listing medications by grouping of the conditions that the medications are used.
- Separate the "Allergies or side effects" field into two separate field lines to eliminate potential confusion and to distinguish between the two.

Conclusion
Overall, the standardized format to the MAP and PML provide valuable information for patients to use in managing their medications and in working with their pharmacist. Again, we appreciate CMS' effort to further improve the functionality and efficiency of the standardized template to improve use and decrease burden as patients and providers of MTM use the document.

Thank you for the opportunity to provide comments on this important issue. We look forward to continuing to work with CMS on this issue. If you have any questions or require additional information, please contact Marcie Bough, Senior Director of Government Affairs at mbough@aphanet.org or by phone at (202) 429-7538.

Sincerely,

Thomas E. Menighan

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

TM/mb

cc: Brian Gallagher, BSPharm, JD, Senior Vice President, Government Affairs
Anne Burns, BSPharm, Senior Vice President, Professional Affairs
Marcie Bough, PharmD, Senior Director, Government Affairs

PHARM MD

July 28, 2011

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

RE: Standardized Format for the Comprehensive Medication Review Action Plan and Summary

Dear Sir/Madam:

Thank you for the opportunity to make comments on the proposed standardized format for the comprehensive medication review action plan and summary. PharmMD's goal is to be the quality leader in medication therapy management (MTM) services. As such, PharmMD expends a great amount of effort towards quality and efficiency in the delivery of these services. PharmMD currently contracts with multiple Medicare and Medicaid health plans and other large groups to deliver MTM services to their patients in accordance with CMS requirements. As a company that focuses solely on MTM and its delivery, this standardized format will directly affect our company and we appreciate the chance to share our feedback.

PharmMD utilizes a three-pronged approach to deliver MTM, involving the patient, physician, and pharmacist. After completion of a medication review, a cover letter, medication action plan, and personal medication record are sent to the patient and their physician. These documents have been developed from industry standards, experience, research, focus groups, and feedback provided by physicians and patients. The comments on the standardized formats for these documents are derived from what we have discovered to work in practice. Comments are divided by each proposed document.

<u>Cover Letter:</u>
A substantial benefit of MTM is the decrease in overall medical costs. The cover letter explains the intent of making sure medications and being taken properly and appropriate but does not state the cost savings opportunity. Cost savings is also an incentive for the patient to take interest in the medication review. Add the benefit of cost savings to the cover letter. To the extent it may be helpful, PharmMD buckets its interventions into three areas:

1. Is the patient on the best medication to treat the patient's medical conditions?
2. Is the patient using the medication correctly and achieving the desired results?
3. Are there opportunities to discontinue any medications or change medications to achieve cost savings?

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We have found that these three areas help to communicate the value to the beneficiary of "What is in it for them" and helps to get them engaged.

Medication Action Plan:

- PharmMD recommends including the medication the suggested action is about.
- Reformat the MAP as a checklist to be more effective and take up less space. Instead of the empty space and "what I did" section, the "what I need to do" section could be listed as a checklist that could be checked off by the patient once completed. For example – If a patient needs to talk to their doctor about a generic medication, the "what I need to do" section would be a checklist that states "Talk to your doctor about taking the generic for this medication." This eliminates additional white space and wasted paper as well.

Medication Record:

- The proposed medication record takes up a lot of paper and only allows for 10 medications. PharmMD recommends creating a table with headings. This will take up less paper and condense the information. For a patient with 30+ medications (which we have seen), it would take 7 pages under this format, but with a table it can be condensed to 3.
- Add a "last filled" section on the medication record to better assess adherence. We have found this to be more important than a start/stop date. Our past experience with start/stop dates includes:
    - Start Dates – Beneficiaries often find it difficult to remember when they started taking the medication. What is the purpose for this field? Does it fulfill a purpose that provides a lot of value?
    - Stop Dates – This is another field that is difficult to include as it is often unknown or once it is known the medication would not be included on the list.
- The "why I use it" section is difficult to fill out especially when forms are created electronically based on medical claims data. Until medication indications are required on prescriptions, including this on a medication record would be difficult. There are too many potential variables and mistakes otherwise. This is especially the case in PDP populations. If possible, where there are opportunities for the beneficiary to fill in the information, this would be recommended. We also have concerns in completion of this field when gathering the information from the patient that this be noted as "patient reported" in case the patient remembers incorrectly. We would not want a condition to be documented that is incorrect but to become "recorded" and somehow carried through the medical system.

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PHARM MD

The PharmMD system creates these documents electronically once a medication review has been completed. Therefore being able to integrate this standardized format into an electronic documentation system is essential to our continued success as the quality leader in delivering Medication Therapy Management services. Please take this into consideration while finalizing the standardized format.

Once again thank you for the opportunity to provide comments on the standardized format. If you have any further questions or require additional information we would be glad to provide further information in writing or in person as is beneficial.

Sincerely,

Bradley P. Tice

Brad Tice, PharmD, FAPhA

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