DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: March 11, 2011

TO: All Part D Sponsors

FROM: Cynthia G. Tudor, Ph.D., Director
Medicare Drug Benefit and C & D Data Group

SUBJECT: Standardized Format for the Comprehensive Medication Review Action Plan and Summary – Request for Comment

The Affordable Care Act (ACA) under Section 10328 specifies changes to Part D Medication Therapy Management (MTM) programs. In particular, this section identifies required interventions, which include an annual comprehensive review of the participating beneficiary's medications, furnished interactively with the beneficiary by a licensed pharmacist or other qualified provider. The comprehensive medication review (CMR) may result in the preparation of a medication action plan or other instructions for the beneficiary. The beneficiary must be given a written or printed summary of the results of the review. The ACA further requires that the Secretary, in consultation with relevant stakeholders, develop a standardized format for the CMR action plan and summary.

In our proposed rule, "Proposed Changes to the Medicare Advantage and the Medicare Prescription Drug Benefit Programs for Contract Year 2012," which was published in the *Federal Register* on November 22, 2010, we also described our plan to work with stakeholders to develop a standardized format for the action plan and summary that may result from the CMR. CMS prepared a draft format based upon an environmental scan and literature review for formats currently in use within the industry for medication review summaries or action plans.

As we consider development of the standardized format for the written or printed summary and action plan, we are soliciting your suggestions and feedback about the attached draft format (see attachment).

The draft format provides templates for the written summary and action plan, and includes three components: Beneficiary Cover Letter, Medication Action Plan (MAP), and Personal Medication List (PML), consistent with MTM forms currently in use. The components must be personalized for the beneficiary and customized for the Part D sponsor or MTM program where indicated by instructions appearing in italicized text. Data fields on the MAP and PML may be expanded or reduced in size as needed for the information being conveyed. Undefined fields are also available on the PML to allow Part D sponsors to provide additional information to meet the

unique needs of each beneficiary beyond the requirements of the basic standardized format, such as remarks or supplemental instructions, and to promote innovation. Text must be written in 12-point or larger serif font, and in easily understandable language rather than medical or technical jargon to the extent possible.

Our tests indicate that the proposed standardized format may be used effectively by all Part D MTM programs for CMRs, targeted medication reviews, and other MTM interventions based upon the ability to customize the content as described above. CMS also believes that MTM providers should consistently address beneficiary concerns, directions and intended medical use for each medication, and goals of therapy, which are key aspects of the CMR encounter and engagement of beneficiaries in their treatment plans. Including this information in the standardized format will significantly improve the value of the MTM program to beneficiaries.

We appreciate your comments and suggestions, and your estimates of the cost and time to implement the standardized format.

We look forward to working with stakeholders and MA organizations and PDP sponsors on the development of the standardized format. Please submit your suggestions and feedback concerning the proposed standardized format to partd_mtm@cms.hhs.gov with "Medication Action Plan" in the subject line by March 25, 2011.

All interested parties will have an opportunity to provide additional comments pursuant to the Paperwork Reduction Act process later this year.

ATTACHMENT

<PLAN/PROVIDER HEADER (LETTERHEAD, NAME, ADDRESS, WEBSITE, LOGOS, BARCODES, ETC.>

<Insert print date>

<Member Name
Address1
Address2
Address3
City, State Zip>

<ADDITIONAL SPACE FOR PLAN/PROVIDER INFORMATION AND OPTIONAL BENEFICIARY IDENTIFIERS, SUCH AS ID # OR DATE-OF-BIRTH>

Dear <*insert member's name*>:

As a member of the <*insert name of Part D Plan*>, you are eligible to participate in our Medication Therapy Management (MTM) program. The MTM program helps selected Medicare beneficiaries use their medications safely and effectively. It also helps make sure that you are responding well to your medications.

On <*insert date of service*>, we reviewed your medications and your medication-related concerns with you, and evaluated your specific health and pharmacy needs. This letter is a summary of your medication review and evaluation, and will remind you of action steps and other information we discussed about your treatment plan. Please share this information with your doctors and other healthcare providers to help them choose the best treatments for you and to update your medication records.

Here are the main points from our review together:

<Using simple language, insert a high-level summary in bullet format of the concerns that were discussed during the session, including acknowledging the beneficiary's success in managing their therapy, and issues raised by the beneficiary and identified by the MTMP reviewer, as applicable, such as:

- *appropriateness of each medication;*
- *goals of therapy;*
- *adherence;*
- *side effects;*
- *untreated conditions;*
- *allergies;*
- *cost and access considerations;*
- *brand-generic issues;*
- *dose and regimen;*
- *medication administration;*
- *self-monitoring;*
- *lifestyle changes;*
- *product storage;*
- *next appointment; and,*
- *any other concerns.*

If applicable, also include a statement that you will contact the beneficiary's doctor about the results of the review, any recommendations and follow-up.>

<PLAN/PROVIDER FOOTER SECTION FOR PLAN/PROVIDER MESSAGING, SUCH AS MEDICARE MARKETING STATEMENT, PRIVACY STATEMENT, LANGUAGE TRANSLATION SERVICES

Please also read the enclosed Medication Action Plan and Personal Medication List.

The Medication Action Plan has steps you should take to help get the most benefit from your medicines and help solve problems we talked about during your review. The Personal Medication List will help you to keep track of your medicines and to take them the right way. Please take your Medication Action Plan and Personal Medication List with you to each appointment with your doctor, and ask your doctor and pharmacist to check and update them at your regular visits, and if you are admitted to the hospital.

If you have any questions or concerns about this letter, the Medication Action Plan, or Personal Medication List, please call *<insert contact information, phone number, days/times, TTY, etc.>*. We look forward to working with you and your doctors to help you stay healthy through the *<insert name of MTMP>*.

Sincerely,

<Insert signature, name, title, etc.>

MEDICATION ACTION PLAN FOR *<Insert Member's name and other identifiers>*

This Medication Action Plan will help you work with your doctor and pharmacist to help get the most benefit from your medicine. Please take this chart with you to each appointment with your doctor. Complete the action steps and write-down the results as you go along. If you have any questions about your Action Plan, please call *<insert contact information, phone number, days/times, etc.>*.

DATE PREPARED: *< Insert date >*

CONCERN – What we talked about: *<insert description of problem or goal>*	
ACTION STEPS – What I should do: *<insert recommendations for patient activities>*	**RESULT** – What I did and when I did it: *<leave blank for patient's notes>*
CONCERN:	
ACTION STEPS:	**RESULT:**
CONCERN:	
ACTION STEPS:	**RESULT:**
CONCERN:	
ACTION STEPS:	**RESULT:**
ADDITIONAL INFORMATION: *<Free-form box for additional notes and recognition of beneficiary's successes to date.>*	

PERSONAL MEDICATION LIST FOR *<Insert Member's name and other identifiers>*

This Personal Medication List was prepared for you based upon our discussion and information we received from *<insert source of information>*. It is important for you to keep this list up-to-date with prescription and over-the-counter medications, vitamins, other supplements, and medication-related devices. Use the blank rows to add information about new products; and include the date you start or stop using a product. Ask your healthcare providers to update this chart during your regular visits. Also, if you need treatment at the hospital or emergency room, be sure to show this list to the hospital staff. If you have any questions or concerns about your Personal Medication List, please call *<insert contact information, phone numbers, days/times, etc.>.*

DATE PREPARED: *< Insert date >*

ALLERGIES:	
ADVERSE REACTIONS:	

PRODUCT: *<Insert generic name (and brand name if applicable), strength, and dosage form>*	
HOW TO USE IT: *<Insert regimen, including dose and frequency, and supplemental instructions as appropriate>*	
DOCTOR: *<Insert prescriber's name, telephone number>*	**START DATE:** *<Insert start date>*
PURPOSE: *<Insert indication or intended medical use>*	**STOP DATE:** *<Insert stop date>*
GOALS OF THERAPY: *<Insert brief description; include attachment if needed>*	
***<INSERT OTHER TITLE(s)>*:** *<Insert additional information, such as remarks, supplemental instructions, product image/identifiers, source of data. This field may be expanded, divided, or deleted>*	

PRODUCT:	
HOW TO USE IT:	
DOCTOR:	**START DATE:**
PURPOSE:	**STOP DATE:**
GOALS OF THERAPY:	
<INSERT OTHER TITLE(S)>:	

PRODUCT:	
HOW TO USE IT:	
DOCTOR:	**START DATE:**
PURPOSE:	**STOP DATE:**
GOALS OF THERAPY:	
***<INSERT OTHER TITLE(s)>*:**	

ADDITIONAL INFORMATION: *<Free-form box for additional notes. May be expanded or deleted.>*

PERSONAL MEDICATION LIST FOR *<Insert Member's name>*, (Continued)

PRODUCT:	
HOW TO USE IT:	
DOCTOR:	**START DATE:**
PURPOSE:	**STOP DATE:**
GOALS OF THERAPY:	
***<INSERT OTHER TITLE(s)>*:**	

PRODUCT:	
HOW TO USE IT:	
DOCTOR:	**START DATE:**
PURPOSE:	**STOP DATE:**
GOALS OF THERAPY:	
***<INSERT OTHER TITLE(s)>*:**	

PRODUCT:	
HOW TO USE IT:	
DOCTOR:	**START DATE:**
PURPOSE:	**STOP DATE:**
GOALS OF THERAPY:	
***<INSERT OTHER TITLE(s)>*:**	

PRODUCT:	
HOW TO USE IT:	
DOCTOR:	**START DATE:**
PURPOSE:	**STOP DATE:**
GOALS OF THERAPY:	
***<INSERT OTHER TITLE(s)>*:**	

PRODUCT:	
HOW TO USE IT:	
DOCTOR:	**START DATE:**
PURPOSE:	**STOP DATE:**
GOALS OF THERAPY:	
***<INSERT OTHER TITLE(s)>*:**	