DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTERS for MEDICARE & MEDICAID SERVICES

CENTER FOR DRUG and HEALTH PLAN CHOICE

DATE: **March 8, 2010**

TO: All Part D Sponsors

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

SUBJECT: Contract Year 2011 Medication Therapy Management Program (MTMP) Submission

Background

In this memo, we describe the process for submitting your MTM program descriptions for contract year (CY) 2011. Each Part D sponsor is required to incorporate a MTMP into their Plan's benefit structure. Annually, sponsors must submit a MTMP description to CMS for review and approval. For approval, a sponsor's MTMP must be in compliance with 42 CFR §423.153(d) and related CMS guidance, including the revised MTMP requirements established in the 2010 Call Letter. A CMS-approved MTMP is one of several required elements in the development of sponsors' bids for CY 2011. The minimum Part D requirements for MTMP, CMS expectations, and a review of information that must be included with the MTMP submission are provided in Attachment 1 at the end of this memo. CMS will monitor Part D sponsors' movement to more restrictive criteria.

Submission

All Part D sponsors, including renewing and new applicant MA-PDs and PDPs, must submit a MTMP by Monday, April 12, 2010, 11:59pm P.S.T. The MTMP requirement does not apply to MA Private Fee for Service (MA-PFFS) organizations, as described in 42 CFR §422.4 (a)(3). However, considering MA-PFFS organizations have an equal responsibility to provide a quality Part D product, CMS encourages MA-PFFS organizations to establish a MTMP to improve quality for Medicare beneficiaries.

The CY 2011 MTMP submission should be submitted through the Health Plan Management System (HPMS) in the MTMP Submission module under "Plan Formularies." This interface was established to enable Part D sponsors to enter, edit, and submit their MTMP descriptions within HPMS at the contract level. A technical user's manual for accessing the HPMS, navigating through the MTMP Submission module, and performing Plan functions is available for download through the HPMS 2011 MTMP submission module.

A CY 2011 MTMP submission template is provided in Attachment 2. This template serves as a guide to the information that must be entered in the HPMS MTMP Submission module. Note that there is a new entry edit in place. If you enter any unprintable characters, such as quotation marks, dashes, or bullets, in any of the free form text fields, these characters will be automatically removed. You will have the ability to verify the revised text prior to saving and

submitting the MTMP, but the removal of these characters should not significantly affect the content of your submission. The purpose is to improve how the submission text is viewed and improve how the submissions are processed on the back end.

The submission gate in HPMS will open on March 29, 2009. The MTM Upload gate will be closed at 11:59pm P.S.T. on April 12, 2010, and will only be reopened if your contract requires resubmission of your MTMP to correct deficiencies. If your contract needs to submit your MTMP outside of the initial submission upload and resubmission processes, please email your request to have the submission gate opened to partd_mtm@cms.hhs.gov.

CMS will communicate with each contract regarding the status of their MTMP review (including if the MTMP requires resubmission to correct deficiencies or if the MTMP meets all of the minimum requirements for CY 2011). Communications will be sent via email to the HPMS MTMP Main Contact and Medicare Compliance Officer. Please ensure that your contact information is up-to-date in HMPS under the Contract Management section. Additionally, semi-annually, CMS posts a list of MTM contacts by state for each Part D contract on the CMS website.

We appreciate your continued cooperation in administering the Medicare drug benefit. Questions regarding the MTM submission process should be sent via email to partd_mtm@cms.hhs.gov. If you have any questions on accessing the HPMS MTMP module, please contact the HPMS Help Desk at 1-800-220-2028.

Attachment 1
Medication Therapy Management Program Requirements

Requirements for Medication Therapy Management Program (MTMP)
Under 42 CFR §423.153(d), a Medicare Part D sponsor must establish a Medication Therapy Management Program (MTMP) that:

- Is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries are appropriately used to optimize therapeutic outcomes through improved medication use;
- Is designed to reduce the risk of adverse events, including adverse drug interactions, for targeted beneficiaries;
- Targets beneficiaries who are enrollees in the sponsor's Part D plan who:
    - Have multiple chronic diseases, AND
    - Are taking multiple Part D drugs, AND
    - Are likely to incur annual costs for covered Part D drugs that exceed a predetermined level specified by the Secretary.
- Is developed in cooperation with licensed and practicing pharmacists and physicians;
- May be furnished by pharmacists or other qualified providers;
- May distinguish between services in ambulatory and institutional settings;
- Describes the resources and time required to implement the program if using outside personnel and establishes the fees for pharmacists or others.

Per the revised in requirements in the 2010 Call Letter, all Part D sponsors must establish a MTMP that:

1. Enrolls targeted beneficiaries using an opt-out method of enrollment only;
    - A beneficiary that meets the targeting criteria would be auto-enrolled and considered to be enrolled unless he/she declines enrollment. The enrolled beneficiaries may refuse or decline individual services without having to disenroll from the MTM program.

2. Targets beneficiaries for enrollment at least quarterly during each year.

3. Targets beneficiaries who:
    - Have multiple chronic diseases; and
        - In defining multiple chronic diseases, sponsors cannot require more than 3 chronic diseases as the minimum number of multiple chronic diseases and sponsors must target at least four of the following seven core chronic conditions:
            - Hypertension;
            - Heart Failure;
            - Diabetes;
            - Dyslipidemia;
            - Respiratory Disease (such as Asthma, Chronic Obstructive Pulmonary Disease (COPD), or Chronic Lung disorders);
            - Bone Disease-Arthritis (such as Osteoporosis, Osteoarthritis, or Rheumatoid Arthritis);
            - Mental Health (such as Depression, Schizophrenia, Bipolar Disorder, or Chronic and disabling disorders).

        - Part D sponsors may continue to choose to target beneficiaries with any chronic diseases or limit enrollment in their MTM program to beneficiaries having specific chronic diseases.

- However, at a minimum, sponsors must target at least 4 of the 7 core chronic diseases. Part D sponsors may target any chronic diseases in addition to the core diseases, but all Part D MTM programs must target at least 4 of these 7 diseases.
- Sponsors are encouraged to consider targeting additional diseases to meet the needs of their patient populations and improve therapeutic outcomes. In applying the criterion, the targeted beneficiary could have any combination of the chronic diseases targeted by the sponsor. As an example, if a sponsor targets beneficiaries with at least two chronic diseases and targets all seven of the core diseases plus five additional diseases, a beneficiary would meet these criteria by having at least two of these twelve diseases in any combination.

- Are taking multiple Part D drugs; and
  - In defining multiple Part D drugs, sponsors cannot require more than 8 Part D drugs as the minimum number of multiple covered Part D drugs.

- Are likely to incur annual costs of at least $3000 for all covered Part D drugs (predetermined level specified by the Secretary).

4. Offers interventions to the participating beneficiary and his/her prescriber. The beneficiary and prescriber interventions may be provided independently, or in combination, to promote coordinated care. Part D sponsors must offer a minimum level of MTM services that includes an interactive component of MTM as well as continued monitoring and follow-up. These services may be furnished by pharmacists or other qualified providers. Sponsors may incorporate passive or 'lower touch' interventions, such as educational newsletters, drug utilization review (DUR) edits, refill reminders, and medication lists into their MTM programs, but these cannot be the sole offerings.

   - At a minimum, Part D sponsors must offer MTM services that include the following:

     a. Offer a comprehensive medication review (CMR) by a pharmacist or other qualified provider at least annually to all targeted beneficiaries enrolled in the MTM program by a pharmacist or other qualified provider. A CMR is a review of a beneficiary's medications, including prescription, over-the-counter (OTC) medications, herbal therapies and dietary supplements, that is intended to aid in assessing medication therapy and optimizing patient outcomes. While initial preparations to assess medication use and identify medication-related problems before the patient interaction may be conducted 'behind the scenes', they are only one piece of the overall comprehensive medication review. CMS recognizes the importance of offering an interactive, person-to-person consultation with the beneficiary for a complete assessment of the beneficiary's needs to improve medication use or outcomes.

This includes three components:

i. Review of medications to assess medication use and identify medication-related problems. This may be conducted person-to-person or 'behind the scenes' by a qualified provider and/or using computerized, clinical algorithms.
ii. Offering to provide to each targeted beneficiary enrolled in the MTM program an interactive, person-to-person consultation performed by a qualified provider. This real-time interaction may be face-to-face or through other interactive methods such as the telephone. This interaction may include further assessment of the beneficiary's medication history and use (could enable sponsors to collect information from the beneficiary, such as OTC medications or supplements, that is outside of the claims data they have access to), health status, clinical information, adverse events, or other issues that could affect medication use or outcomes.
iii. Implementation of a systematic process to summarize the interactive consultation and provide an individualized written "take-away" to the beneficiary such as a personal medication record, reconciled medication list, action plan, recommendations for monitoring, education, or self-management, etc.

b. For ongoing monitoring, perform targeted medication reviews for all beneficiaries enrolled in the MTM program, no less often than quarterly, to assess medication use, monitor whether any unresolved issues need attention, new drug therapy problems have arisen, or if the beneficiary has experienced a transition in care. Part D sponsors must assess the findings of these reviews to determine if a follow-up intervention is necessary and if the intervention is warranted for the beneficiary and/or prescriber. These assessments could be person-to-person and/or system generated. The follow-up interventions should be interactive, if possible, but may be delivered via the mail or other means. The sponsor may determine how to implement based on the specific needs or medication use issues of the enrolled beneficiary.

c. Offer interventions targeted to prescribers to resolve medication-related problems or other opportunities to optimize the targeted beneficiary's medication use. These interactions may be passive (e.g. faxed, mailed) or interactive when determined necessary.

- As stated above, the enrolled beneficiaries may refuse or decline individual services without having to disenroll from the program. For example, **if an enrolled beneficiary declines the annual CMR or another follow-up intervention, the sponsor should still offer interventions to the prescriber and perform targeted medication reviews at least quarterly to assess medication use on an on-going basis.**

- Note: For targeted beneficiaries enrolled in the MTM program that are in a LTC setting, sponsors are not required to offer the interactive CMR component, but still must perform quarterly medication reviews and offer interventions targeted to the beneficiaries' prescribers.

5. Measures and analyzes MTMP outcomes and reports details to CMS through our Part D reporting requirements.

CMS Expectations

- Once enrolled, a beneficiary will not be disenrolled from the MTMP program if they no longer meet one or more of the MTMP eligibility criteria as defined above and will remain in the MTMP program for the remainder of the calendar year.
- Sponsors' MTMP will serve and provide interventions for enrollees who meet all three of the required criteria as defined above regardless of setting (e.g., ambulatory, long term care, etc.)
- Sponsors' MTMP will not include discriminatory exclusion criteria. If an enrollee meets all three of the required criteria as described by your plan, the enrollee should be eligible for MTM intervention.
- Sponsors will consider the provision of other prescription drug quality improvement interventions to beneficiaries who do not meet all three of the required MTMP criteria as described by your plan, however, these cannot be considered for MTM reimbursement by CMS.
- Sponsors will put into place safeguards against discrimination based on the nature of their MTM interventions (i.e., TTY if phone based, Braille if mail based, etc.)
- Sponsors will promote continuity of care by performing an end-of-year analysis that identifies current MTM program participants who will continue to meet the eligibility criteria for the next program year for the same Plan.
- Sponsors will have procedures in place to drive participation and follow-up with beneficiaries that do not respond to initial offers for MTM services.
- Sponsors will consider using more than one approach when possible to reach all eligible patients who may wish to receive MTM services.
- Sponsors will analyze and evaluate their MTMP and make changes to continuously improve their programs.

Information that MUST be included with the MTMP Application

- Targeting Criterion #1: Multiple Chronic Diseases
    - Provide the minimum number of distinct chronic diseases a beneficiary must have to meet this criterion. (Note: this minimum threshold is required to be 2 or 3.)
    - Provide the specific name of each chronic disease that will be targeted or if any chronic disease will be targeted.

  Example 1: A beneficiary must have any 2 or more chronic diseases.
  Example 2: A beneficiary must have 2 or more chronic diseases. The following chronic diseases will be targeted: Respiratory Disease-Asthma, Diabetes, Chronic Heart Failure, Hypertension.
  Example 3: A beneficiary must have 3 or more chronic diseases. The following chronic diseases will be targeted –Respiratory Disease-Asthma, Respiratory Disease-COPD, Bone Disease-Arthritis-Rheumatoid Arthritis, Dyslipidemia, Mental Health-Depression, Autoimmune disorders, HIV/AIDS.

- Targeting Criterion #2: Multiple Covered Part D Drugs
    - Provide the minimum number of covered Part D drugs that a beneficiary must have filled to meet this criterion. (Note: this minimum threshold is required to be any number ≥ 2 and ≤ 8.)
    - Provide the type of covered Part D drugs that applies (i.e. any Part D drug, chronic/ maintenance drugs, disease-specific, specific Part D drug classes).

    Example: A beneficiary must have filled any 5 or more distinct covered Part D drugs.
    Example 2: A beneficiary must have filled any 2 or more distinct covered Part D chronic/ maintenance drugs.

- Targeting Criterion #3: Part D drug cost of $3,000
    - Provide the analytical procedure used to determine if a beneficiary is likely to incur annual costs of at least $3,000 for all covered Part D drugs.
    - Provide the specific thresholds per time, formula or describe in detail the predictive model used to identify beneficiaries who are likely to incur this annual cost.

    Example 1: $750 previous quarter.
    Example 2: Average monthly prescription drug cost is greater or equal to $250. Average monthly prescription drug costs is calculated by totaling the total gross drug cost amount for the last 90 days/90) x 30.

- Targeting frequency and data evaluated for targeting.
    - Provide the frequency of identifying beneficiaries which is required to be no less frequently than quarterly. For example, daily, weekly, monthly, or quarterly targeting frequencies would meet this requirement.
    - Provide the data evaluated for targeting eligible beneficiaries. Examples include drug claims, medical claims, lab data, etc.

- Methods of enrollment and disenrollment. This will automatically default to opt-out only.

- Type, frequency and recipient of interventions.
    - Provide the recipient of MTM interventions. This will automatically default to beneficiary and prescriber. Other recipients may be provided in addition.
    - Provide the specific beneficiary interventions.
        - This will automatically default to review of medications, interactive, person-to-person consultation, and individualized, written summary of the interactive consultation.
        - Selections must be provided for the delivery method(s) for the interactive consultation and the type(s) of written takeaways.
        - Targeted medication reviews at least quarterly will also be defaulted. Other beneficiary interventions may be provided in addition.
    - Provide the specific prescriber interventions.
        - This will automatically default to prescriber interventions to resolve medication-related problems or optimize therapy.
        - Selections must be provided for the delivery method(s) for the prescriber consultation.
        - Other prescriber interventions may be provided in addition.

    - Provide a detailed description of how your program will provide the MTM interventions describing interventions for both beneficiaries and prescribers, an annual comprehensive medication review for the beneficiary, which includes a review of medications, interactive, person-to-person consultation, and an individualized, written summary of interactive consultation, and quarterly targeted medication reviews.

- Resources and who will provide MTM services.
    - Provide the type of personnel that will be providing the MTM services such as in-house staff or the type of outside personnel.
    - Provide the type of qualified provider such as pharmacist, physician, or registered nurse.

- How fees will be established for MTMP if using outside personnel. If establishing fees for pharmacists or others, provide the amount of fee respective to MTMP management and the fee paid for the provider of the MTM.
    - Provide if fees are covered as part of the services of the global PBM or vendor contract (without being priced out separately) or if fees are priced out separately.
    - If the fees are priced out separately and the Plan is charged a fee by the PBM or vendor within the contract, then a description of the specific fees needs to be reported.
        - Provide the specific fee(s), billing method(s) such as per minute or per service, and an optional description.

- Methods of documenting and measuring MTMP outcomes.
    - Provide the outcomes measured.

Attachment 2
Medication Therapy Management Program Submission Template for Contract Year 2011

- This template serves as a guide to the information that must be entered in the Health Plan Management System (HPMS) Medication Therapy Management Program (MTMP) submission module. Refer to the Technical User's Manual in HPMS for more specific instructions and screen shots.
- Note that there is a new entry edit in place. If you enter any unprintable characters, such as quotation marks, dashes, or bullets, in any of the free form text fields, these characters will be automatically removed. You will have the ability to verify the revised text prior to saving and submitting the MTMP, but the removal of these characters should not significantly affect the content of your submission. The purpose is to improve how the submission text is viewed and improve how the submissions are processed on the back end.

I. Policies and Procedures

A. Targeting Criteria for Eligibility in the MTMP:

1) Multiple Chronic Diseases:
   a) Minimum number of chronic diseases: [Note: Must be 2 OR 3]
   b) Chronic disease(s) that apply:
   [ ] Any chronic disease applies **OR**
   [ ] Specific chronic diseases apply (Select all that apply)

	CORE: Bone Disease-Arthritis-Osteoporosis		CORE: Respiratory Disease-Asthma
	CORE: Bone Disease-Arthritis-Osteoarthritis		CORE: Respiratory Disease-COPD
	CORE: Bone Disease-Arthritis-Rheumatoid Arthritis		CORE: Respiratory Disease-Chronic Lung Disorders
	CORE: Chronic Heart Failure		CORE: Mental Health-Depression
	CORE: Diabetes mellitus		CORE: Mental Health-Schizophrenia
	CORE: Dyslipidemia		CORE: Mental Health-Bipolar Disorder
	CORE: Hypertension		CORE: Mental Health-Chronic and disabling
	Alzheimer's disease		End-stage liver disease
	Anemia		End-stage renal disease requiring dialysis
	Anticoagulation		GI/Reflux/Ulcer conditions
	Autoimmune disorders		Hepatitis C
	BPH		HIV/AIDS
	Cancer		Multiple Sclerosis
	Cardiovascular disorders		Parkinson's disease
	Cerebrovascular disease		Severe hematologic disorders
	Chronic alcohol and other drug dependence		Neurologic disorders
	Chronic pain		Stroke
	Dementia		Other:
	Other:		Other:
	Other:		Other:
	Other:		Other:

2) Multiple Covered Part D Drugs:
   a) Minimum number of covered Part D drugs: *[*Note: Must be≥ 2 and ≤ 8]
   b) Type of covered Part D drugs that apply :
   [ ] Any Part D drug applies **OR**
   [ ] Chronic/maintenance drugs apply **OR**
   [ ] Disease-specific drugs apply related to chronic diseases **OR**
   [ ] Specific Part D drug classes apply (Select all that apply)

	ACE-Inhibitors		Beta-blockers
	Alpha blockers		Bronchodilators
	Angiotensin II receptor blockers (ARBs)		Calcium channel blockers
	Anticoagulants		Disease-Modifying Anti-Rheumatic Drugs (DMARDs)
	Antidepressants		Diuretics
	Antiemetics		Insulins
	Antihyperlipidemics		Interferons
	Antihypertensives		Oral hypoglycemics
	Antineoplastics		Proton Pump Inhibitors
	Antipsychotics		Selective serotonin reuptake inhibitors (SSRIs)
	Antiretroviral therapy		Tumor Necrosis Factors (TNFs)
	Other:		Other:
	Other:		Other:
	Other:		Other:

3) Incurred Cost for Covered Part D Drugs:
   a) Description of the analytical procedure used to determine if a beneficiary is likely to incur annual costs of at least $3,000 for all covered Part D drugs. When applicable, this should include the specific thresholds or formula. (Select all that apply)
   [ ] Specific Threshold and Frequency
      [ ] $750 previous quarter
      [ ] $250 previous month
      [ ] $3,000 previous 12 months
      [ ] Other:
   [ ] Formula:
   [ ] Other:

B. Targeting
Frequency:
(Select one)
[ ] Daily
[ ] Weekly
[ ] Every other week
[ ] Monthly
[ ] Every other month
[ ] Quarterly

Data evaluated for targeting:
(Select all that apply)
[ ] Drug claims
[ ] Medical claims
[ ] Lab data
[ ] Information collected from beneficiaries
[ ] Health Risk Assessment
[ ] Other:

C. Enrollment/ Disenrollment
[X] Opt-out only *[*Automatically selected-cannot be changed]

D. Interventions
Recipient of interventions:
(Select all that apply)
[X] Beneficiary [Automatically selected-cannot be changed]
[X] Prescriber [Automatically selected-cannot be changed]
[ ] Other:

Specific beneficiary interventions:
(Select all that apply)
[X] Comprehensive Medication Review, annual [Automatically selected-cannot be changed]
    [X] Review of medications [Automatically selected-cannot be changed]
    [X] Interactive, person-to-person consultation [Automatically selected-cannot be changed]
        (Select all that apply)
            [ ] Face-to-face
            [ ] Phone
            [ ] Other:
    [X] Individualized, written summary of interactive consultation [Automatically selected-cannot be changed]
        (Select all that apply)
            [ ] Personal medication list
            [ ] Reconciled medication list
            [ ] Action plan
            [ ] Recommendations
            [ ] Other:
[X] Targeted medication reviews, at least quarterly [Automatically selected-cannot be changed]
[ ] General education newsletter, beneficiary
[ ] Refill reminder, beneficiary
[ ] Referral: Disease Management
[ ] Referral: Specialty Management
[ ] Referral: Case Management
[ ] Other:
[ ] Other:
[ ] Other:

Specific prescriber interventions:
(Select all that apply)
[X] Prescriber interventions to resolve medication-related problems or optimize therapy [Automatically selected-cannot be changed]
(Select all that apply)
[ ] Phone consultation
[ ] Mailed consultation
[ ] Faxed consultation
[ ] Emailed consultation
[ ] Other:
[ ] General education newsletter, prescriber
[ ] Patient Medication list
[ ] Other:
[ ] Other:
[ ] Other:
[ ] Other:

Specific other recipient interventions: [Only appears if selected 'Recipient of interventions: Other']
(Select all that apply)
[ ] Other:
[ ] Other:
[ ] Other:
[ ] Other:

(Provide detailed description of the type, frequency and recipient of intervention(s).)
[Text Box]

E. Resources
Provider of MTM services
(Select all that apply)
[ ] In-house staff
[ ] Pharmacist
[ ] Physician
[ ] Registered Nurse
[ ] Other:
[ ] Outside personnel
[ ] PBM Name of PBM:
[ ] Pharmacist
[ ] Physician
[ ] Registered Nurse
[ ] Other:
[ ] Disease Management vendor Name of vendor:
[ ] Pharmacist
[ ] Physician
[ ] Registered Nurse
[ ] Other:
[ ] Medication Therapy Management vendor Name of vendor:
[ ] Pharmacist
[ ] Physician
[ ] Registered Nurse
[ ] Other:
[ ] Community pharmacists
[ ] Long Term Care pharmacists
[ ] Other:

F. Fees [Only appears if Outside personnel selected in Resources]
(Select one)
[ ] Fees are covered as part of the services of the global PBM or vendor contract (without being priced out separately) **OR**
[ ] Fees priced out separately (Enter fee(s) and billing type(s) that apply)

Specific fee	Billing Method	Description (optional)
$00000.00	Use drop Down Options*	
$00000.00	Use drop Down Options*	
$00000.00	Use drop Down Options*	
$00000.00	Use drop Down Options*	
$00000.00	Use drop Down Options*	

*Use drop Down Options:
Flat rate per service
Capitated rate
Per member
Per member per month
Per hour
Per minute
Per claim
Other:

G. Outcomes Measured
(Select all that apply)
[X] Part D Reporting Requirements. [Automatically selected-cannot be changed]
[ ] Medication adherence
[ ] Medication persistence
[ ] Drug-drug interactions
[ ] High risk medications (drugs to be avoided in elderly)
[ ] Polypharmacy
[ ] Overutilization
[ ] Underutilization
[ ] Medication issues resolved
[ ] Overall prescription drug costs
[ ] Overall medical costs
[ ] Overall healthcare costs
[ ] Emergency department visits
[ ] Hospital admissions
[ ] Length of hospital stay
[ ] Health Status Survey/ Improvements
[ ] Cost avoidance savings
[ ] Patient understanding
[ ] Self-management
[ ] Member satisfaction
[ ] Provider satisfaction
[ ] Other:

H. Additional Information 1 (Optional)
[Text Box]

I. Additional Information 2 (Optional)
[Text Box]