

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CENTER FOR DRUG and HEALTH PLAN CHOICE

TO: All Part D Sponsors

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

SUBJECT: Changes to Part D Sponsors' Medication Therapy Management Program (MTMP)-REVISED

DATE: August 5, 2008

Part D Sponsors are required to establish a Medication Therapy Management Program (MTMP) designed to ensure that covered Part D drugs are appropriately used to optimize therapeutic outcomes through improved medication use and reduced risk of adverse events. Annually each spring, CMS evaluates and approves Part D Sponsor's MTMP for compliance with the current minimum requirements for the upcoming program year. A CMS-approved MTMP is required for all approved Part D Plan Sponsors except 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.

Part D Sponsors have flexibility to develop and implement a MTMP that can best meet the needs of their specific patient populations and achieve the best therapeutic outcomes. To promote evolving Medication Therapy Management best practices and to consider the best interests of the Medicare beneficiary, CMS will allow certain mid-year changes to the Part D Sponsors' approved MTMP, if requested.

The following instructions replace the previous instructions provided on August 29, 2006 to all Part D Sponsors.

Medication Therapy Management Program (MTMP) Changes

Q: What changes can Part D Sponsors make to their CMS-approved MTMP during the program year OR prior to the start of the upcoming program year?

A: Part D Sponsors have flexibility to develop and implement a MTMP that can best meet the needs of their specific patient populations and achieve the best therapeutic outcomes. To promote evolving MTM best practices and to consider the best interests of the Medicare beneficiary, CMS will allow certain changes to Part D Sponsors' MTMPs, if requested. Negative changes will generally not be accepted. Part D Sponsors may have experiences during the current contract year that identify the need for changes to the current program year MTMP or

to the upcoming contract year program. All proposed Medication Therapy Management Program changes must be submitted to CMS for review and approval prior to the implementation of requested changes.

We have a 4 part policy regarding MTMP changes during the program year OR prior to the start of the upcoming program year (after Sponsors receive approval for their upcoming year MTMP applications).

1. Part D Sponsors may make *positive* changes to the plan-designed eligibility criteria for multiple chronic diseases, multiple covered Part D drugs, or analytical procedures used to determine if a beneficiary is likely to incur annual costs in excess of a predetermined level as specified by the Secretary. These changes would make the eligibility more inclusive and could increase the number of beneficiaries eligible to receive Part D MTM services. Positive changes may include:
 - a. Decreasing the minimum number of multiple chronic diseases.
 - b. Expanding the list of specific chronic diseases that apply
 - c. Decreasing the minimum number of multiple covered Part D drugs.
 - d. Expanding the list of specific covered Part D drugs, or types of drugs, that apply
2. Part D Sponsors may make program enhancements or maintenance changes that include changes to:
 - a. Method of beneficiary enrollment/disenrollment or identification to increase or promote ease of beneficiary participation.
 - b. Expand the levels of intervention or service provided to participating targeted beneficiaries.
 - c. Methods of documenting and measuring outcomes.
3. Part D Sponsors may make changes to the following:
 - a. The provider of MTM services,
 - b. Any fee schedules established for pharmacists and other MTM providers if using outside personnel. The CMS will request that Part D Sponsors disclose the newly established fees for outside personnel.
4. Part D Sponsors may not make any negative changes to their MTMP. While the following list is not exhaustive, potentially negative changes include changes that:
 - a. Promote discriminatory or exclusionary practices.
 - b. Decrease the number of enrollees eligible for MTM Services
 - c. Lower quality or robustness of MTM services

Q: Can Part D Sponsors adjust their bid based on changes to their CMS-approved MTMP?

A: No. A CMS-approved MTMP is required for all approved Part D Plan Sponsors, other than Part D sponsors whose only plans are PFFS plans. CMS considers MTMP to be an administrative cost that is included in each plan's bid and premium. Part D Sponsors may not adjust their bids based on requested changes to their CMS-approved MTMP.

Q: How should Part D Sponsors submit a request to make a change to their MTMP?

A: Annually each spring, CMS evaluates and approves Part D Sponsor's MTMP for compliance with the current minimum requirements for the upcoming program year. A CMS-approved MTMP is a required for all approved Part D Plan Sponsors with the exception of PFFS plans who do not establish an MTMP. Once approved by CMS, limited changes to the Part D Sponsors' MTMP may be allowed in accordance with CMS policy. All proposed Medication Therapy Management Program changes must be submitted to CMS for review and approval prior to the implementation of requested changes in the manner described below. Part D Sponsors must attest that any approved MTM marketing materials are not impacted by the proposed change or, alternatively, will be submitted and approved by CMS as necessary prior to implementation of the change.

Medication Therapy Management Program (MTMP) Changes During Program Year

MTMP requests for changes during the program year may be submitted to CMS during the first 10 days of the last month of the quarter. Specifically, requests may be made during any of the three Update Cycle windows:

- March 1-March 10
- June 1-June 10
- September 1-September 10

For MTMP change requests for CY2008 MTM programs ONLY:

1. Complete the MTMP Change Request Form
2. Revise the MTMP description (using the 2008 MTMP template.)
3. Submit both the MTMP Change Request Form and the entire (revised) MTMP in WORD format electronically to partd_mtm@cms.hhs.gov.

NOTE: If one MTMP change request applies to multiple contract IDs, one MTMP Change Request Form and attached program may be submitted which lists all applicable contract IDs.

For MTMP change requests for CY2009 MTM programs:

1. Complete the MTMP Change Request Form
2. Submit the MTMP Change Request Form in WORD format electronically to partd_mtm@cms.hhs.gov.
3. Edit the MTMP entered through the Health Plan Management System (HPMS) in the MTMP Submission module under "Plan Formularies."

NOTE: If one MTMP change request applies to multiple contract IDs, one MTMP Change Request Form may be submitted which lists all applicable contract IDs.

Medication Therapy Management Program (MTMP) Changes Prior to Program Year

Requests for changes to existing MTMPs that would be effective for an upcoming program year should be submitted to CMS during the following Update Cycle window:

- September 1 and September 10.

For MTMP change requests for CY2009 MTM programs:

1. Complete the MTMP Change Request Form
2. Submit the MTMP Change Request Form in WORD format electronically to partd_mtm@cms.hhs.gov.
3. Edit the MTMP entered through the Health Plan Management System (HPMS) in the MTMP Submission module under "Plan Formularies."

NOTE: If one MTMP change request applies to multiple contract IDs, one MTMP Change Request Form and attached program may be submitted which lists all applicable contract IDs

Q: How will I know if my MTMP change request has been approved?

Part D Sponsor's will receive an email correspondence regarding the approval of the revised MTMP. Part D plans must not implement such changes until they receive explicit notification of approval from CMS and must not submit any changes to marketing material until receiving explicit and affirmative CMS approval. Depending upon the number of submitted requests, plans should expect a response within 30 days.

Q: Where can I find the MTMP Change Request Form?

A: The form is attached with this Memo and will be made available on our website at the following location:

www.cms.hhs.gov > Medicare > Prescription Drug Coverage Contracting > Medication Therapy Management

We appreciate your continued cooperation in administering the Medicare drug benefit. Questions regarding the MTM Change Request 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.

Medication Therapy Management Program (MTMP) Change Request Form

- This MTMP Change Request form should be used to communicate Medication Therapy Management Program (MTMP) changes to CMS for review.
- Completed change request form should be emailed to partd_mtm@cms.hhs.gov.
- The submitted MTMP should be revised along with the change request form.
- Part D Sponsors must attest that any approved MTM marketing materials are not impacted by the proposed change or such marketing materials will be submitted and approved by CMS as necessary prior to implementation of the change.

Contract ID(s):

Organization Name:

MTMP Main Contact Name:

MTMP Main Contact Phone Number:

MTMP Main Contact Email Address:

MTMP Program Year (yyyy):

Effective date of MTMP change (mm/dd/yyyy):

Within the appropriate section, provide a brief description and reason for the MTMP change requested:

| Section | Brief description of MTMP change and reason |
|---|---|
| Eligibility Criteria | |
| Identification | |
| Method of enrollment or disenrollment | |
| Interventions | |
| Provider of MTM services/ Resources: | |
| Fees | |
| Outcomes | |
| Other | |

I attest that the following change(s) either do not impact approved MTM marketing materials or such marketing materials will be submitted and approved by CMS as necessary prior to implementation of the change.

(Name)

(Title)

(Date)