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TO: All Part D Sponsors and Capitated Financial Alignment Demonstration Contracts

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

SUBJECT: CY 2013 Medication Therapy Management Program Guidance and Submission Instructions

DATE: April 10, 2012

This memorandum provides guidance to Part D sponsors and organizations interested in offering capitated financial alignment demonstration plans regarding contract year (CY) 2013 Medication Therapy Management (MTM) programs including:

- Information to assist sponsors with the submission of CY 2013 MTM programs;
- The requirements for establishing MTM programs for CY 2013; and
- Implementation instructions for the written summary in CMS’ standardized format which must be provided following each comprehensive medication review (CMR) beginning no later than January 1, 2013.

All MTM program requirements applicable to Part D sponsors will be applicable to capitated financial alignment demonstration contracts. All references to Part D sponsors in this guidance should be assumed to extend to demonstration contracts.

2013 Medication Therapy Management (MTM) submission information

The CY 2013 MTM program submission deadline is **May 7, 2012** for all Part D sponsors. The submission deadline is May 25, 2012 only for organizations interested in offering capitated financial alignment demonstration plans.

Key Calendar Dates

| Action | Part D Sponsors* | Organizations Interested in Offering Capitated Financial Alignment Demonstration Plans |
|--|---------------------------|--|
| Release of the CY 2013 MTM Program submission module in HPMS | April 23, 2012 | May 18, 2012 |
| 2013 MTM Program Submission Deadline | May 7, 2012, 11:59pm PDT. | May 25, 2012, 11:59pm PDT. |

*Includes renewing and new applicant Medicare Advantage Prescription Drug Plans (MA-PDs) and stand-alone Prescription Drug Plans (PDPs).

A CMS approved MTM program is one of several required elements in the development of a Medicare Part D sponsor's bid. Annually, sponsors must submit an MTM program description to CMS for review and approval. CMS evaluates each program description as part of a Part D quality improvement requirement (42 CFR §423.153(d)), to ensure that it meets the current minimum requirements for the program year. The CY 2013 Part D requirements and expectations are described later in this memo.

This requirement does not apply to MA Private Fee for Service (MA-PFFS) organizations or PACE organizations. However, considering MA-PFFS organizations have an equal responsibility to provide a quality Part D product, CMS encourages MA-PFFS organizations to establish an MTM program to improve quality for Medicare beneficiaries.

The CY 2013 MTM program submission should be submitted through the Health Plan Management System (HPMS) in the MTM Program Submission module under "Plan Formularies." This interface was established to enable Part D sponsors to enter, edit, and submit their program descriptions within HPMS at the contract level. A technical user's manual titled, HPMS CY 2013 MTM Program User's Guide, is available for download through the CY 2013 MTM Program Submission module under Documentation. Sponsors should refer to the user's manual for accessing the HPMS, navigating through the MTM Program Submission module, and performing Plan functions. A submission template is provided in Attachment 1. This template serves as a guide to the information that must be entered in the HPMS MTM Program Submission module. Additional instructions regarding the information that must be included in the submission are described in Attachment 2.

CMS will communicate with each sponsor regarding the status of the review of their MTM program, including if resubmission is required to correct deficiencies or if the program meets all of the minimum requirements for CY 2013. Communications will be sent via email to the 2013 HPMS MTM Program Main Contact and Medicare Compliance Officer. Sponsors should ensure that their contact information is up-to-date in HPMS under the Contract Management section. Additionally, CMS posts a list of MTM contacts by state for each Part D contract on the CMS website.

The submission gates will only be reopened if your contract requires resubmission of your MTM program to correct deficiencies. If your contract needs to submit your program 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**.

All changes to a Part D sponsors' approved MTM program for a given contract year must be submitted to CMS for review and approval prior to the implementation of the changes. The instructions for submitting an MTM program change request are posted on the CMS MTM web page at [www.cms.gov](http://www.cms.gov/Medicare/Prescription-Drug-Coverage/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html) > Medicare > Prescription Drug Coverage Contracting > Medication Therapy Management (<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html>).

2013 Medication Therapy Management (MTM) program requirements

The following guidance aligns the revised Part D MTM requirements in 42 CFR §423.153(d) per the April 2012 final rule effective January 1, 2013, the 2013 Call Letter, and previous CMS guidance, including Chapter 7 of the Prescription Drug Benefit Manual. The manual will be updated to reflect the revised requirements.

A Part D sponsor must have established an MTM program that—

- Is designed to ensure that covered Part D drugs prescribed to targeted beneficiaries, as described below, 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;
- May be furnished by a pharmacist or other qualified provider;
- May distinguish between services in ambulatory and institutional settings; and
- Must be developed in cooperation with licensed and practicing pharmacists and physicians.

MTM is a patient-centric and comprehensive approach to improve medication use, reduce the risk of adverse events, and improve medication adherence. Therefore, the programs include high-touch interventions to engage the beneficiary and their prescribers.

In general, each program should include prescriber interventions to promote coordinated care, an interactive comprehensive medication review and discussion with the beneficiary to assess their medication therapies and creation of a medication action plan, and frequent monitoring and follow-up of the beneficiaries' medication therapies.

Enrollment and Targeting

Sponsors must enroll targeted beneficiaries using an opt-out method of enrollment only. Therefore, sponsors must auto-enroll the targeted beneficiaries when they meet the eligibility criteria, and they are considered enrolled unless he/she declines enrollment. The enrolled beneficiaries may refuse or decline individual services without having to disenroll from the MTM program. Sponsors should not wait for program acceptance (such as a returned enrollment mailing or affirmation via the phone) from the beneficiary to offer the required minimum MTM services. Once enrolled, sponsors should not disenroll a beneficiary from the MTM program if they no longer meet one or more of the three eligibility criteria as defined below. Beneficiaries should remain enrolled in the program for the remainder of the calendar year.

Sponsors are expected to use more than one approach when possible to reach all eligible targeted beneficiaries to offer MTM services versus only reaching out via passive offers. Sponsors may increase beneficiary engagement by following up with beneficiaries who do not respond to initial offers (e.g. by providing telephonic outreach after mailed outreach).

Sponsors must target beneficiaries for enrollment in the MTM program at least quarterly during each plan year. Part D sponsors are also expected to 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. This targeting could be done to auto-enroll eligible beneficiaries in the plan's MTM program early in the next program year in order to prevent interruption of MTM interventions.

Targeted Beneficiaries

Targeted beneficiaries for the MTM program are enrollees in the sponsor's Part D plan who meet all of the following criteria. Sponsors should not implement discriminatory exclusion criteria; if an enrollee meets all three of the required criteria as specified by the sponsor, the enrollee should be enrolled into the MTM program.

1. Have multiple chronic diseases, with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment;

In defining multiple chronic diseases, sponsors cannot require more than 3 chronic diseases as the minimum number of chronic diseases that a beneficiary must have to be eligible for the MTM program. Sponsors may set this minimum threshold at 2 or 3.

Part D sponsors may target beneficiaries with any chronic diseases or target beneficiaries with specific chronic diseases. However, if sponsors choose to target beneficiaries with specific chronic diseases, they must include at least five of the following nine core chronic conditions:

- Alzheimer's Disease;
- Chronic Heart Failure (CHF);
- Diabetes;
- Dyslipidemia;
- End-Stage Renal Disease (ESRD);
- Hypertension;
- 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).

Sponsors are encouraged to consider including additional diseases in their targeting criteria to meet the needs of their patient populations and improve therapeutic outcomes. Sponsors should target beneficiaries with any combination of the chronic diseases included in their criteria. For example, if a sponsor targets beneficiaries with at least two chronic diseases and includes seven of the core diseases plus five additional diseases, a beneficiary would meet the criteria by having at least two of these twelve diseases in any combination.

2. Are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment;

In defining multiple Part D drugs, sponsors cannot require more than 8 Part D drugs as the minimum number of Part D drugs that a beneficiary must have filled to be eligible for the MTM program. Sponsors may set this minimum threshold at any number equal to or between 2 and 8.

3. Are likely to incur the following annual Part D drug costs: For 2013, costs for covered Part D drugs greater than or equal to \$3,144.

Part D sponsors are reminded that the CMS requirements for targeting beneficiaries for the MTM program are the floor, and not the ceiling. Therefore, sponsors are encouraged to optimize their criteria to target beneficiaries who are most likely to benefit from access to MTM services or to offer MTM program services to an expanded population of beneficiaries who do not meet the eligibility criteria per CMS' specifications. Sponsors should not restrict their MTM eligibility criteria to limit the number and percent of beneficiaries who qualify for these programs.

Required MTM Services

Plan sponsors must offer a minimum level of MTM services to each beneficiary enrolled in the program that includes all of the following:

1. Interventions for both beneficiaries and prescribers.
2. An annual comprehensive medication review (CMR) with written summaries in CMS' standardized format.
 - o The beneficiary's CMR must include an interactive, person-to-person, or telehealth consultation performed by a pharmacist or other qualified provider; and may result in a recommended medication action plan.
 - o If a beneficiary is offered the annual CMR and is unable to accept the offer to participate, the pharmacist or other qualified provider may perform the CMR with the beneficiary's prescriber, caregiver, or other authorized individual.
3. Quarterly targeted medication reviews (TMRs) with follow-up interventions when necessary.

The beneficiaries enrolled in the MTM program may refuse or decline individual services without having to disenroll from the program. For example, if an enrolled beneficiary declines the annual CMR, the sponsor is still required to offer interventions to the prescriber and perform TMRs at least quarterly to assess medication use on an on-going basis. In addition, sponsors should not wait for the beneficiary to accept the offer for the CMR before performing TMRs or providing interventions to the beneficiary's prescriber. Also, sponsors are expected to put in place safeguards against discrimination based on the nature of their MTM interventions (i.e., TTY if phone based, Braille if mail based, etc).

Comprehensive Medication Review (CMR)

Sponsors must offer a CMR to all beneficiaries enrolled in the MTM program at least annually, including beneficiaries in long-term care (LTC) settings (beginning in 2013). Plan sponsors are expected to actively engage beneficiaries to increase the number of CMRs delivered to MTM enrollees, not just “offer” CMRs.

Sponsors should offer to provide a CMR to newly targeted beneficiaries (i.e., beneficiaries not enrolled in the sponsors’ MTM program during the previous contract year) as soon as possible after enrollment into the MTM program, but no later than 60 days after being enrolled in the MTM program. For MTM enrollees who were enrolled in the MTM program during the previous contract year and continue to meet the criteria for the current contract year, sponsors should offer the CMR within one year of the last CMR offer.

Each CMR must include an interactive, person-to-person, or telehealth medication review and consultation of the beneficiary’s medications (including prescriptions, over-the-counter (OTC) medications, herbal therapies, and dietary supplements) performed in real-time by a pharmacist or other qualified provider with a summary of the results of the review provided to the targeted individual.

We expect the CMR meets the following professional service definition:

A CMR is a systematic process of collecting patient-specific information, assessing medication therapies to identify medication-related problems, developing a prioritized list of medication-related problems, and creating a plan to resolve them with the patient, caregiver and/or prescriber.

A CMR is an interactive person-to-person or telehealth medication review and consultation conducted in real-time between the patient and/or other authorized individual, such as prescriber or caregiver, and the pharmacist or other qualified provider and is designed to improve patients’ knowledge of their prescriptions, over-the-counter (OTC) medications, herbal therapies and dietary supplements, identify and address problems or concerns that patients may have, and empower patients to self manage their medications and their health conditions.

This definition, adapted from the National MTM Advisory Board definition, builds upon the definition in the Core Elements of an MTM Service model. Furthermore, CMS encourages sponsors to review the Core Elements of an MTM Service Model¹ and the Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient

¹ American Pharmacists Association, National Association of Chain Drug Stores Foundation. Medication therapy management in community pharmacy practice: core elements of an MTM service (version 2.0). March 2008. Accessed March 19, 2012 at: <http://www.pharmacist.com/AM/Template.cfm?Section=Pharmacists&TEMPLATE=/CM/ContentDisplay.cfm&CONTENTID=19013>.

Outcomes Resource Guide² for examples of industry standards of care for delivering MTM and CMRs.

Cognitively Impaired Beneficiaries (in any setting of care)

While providers are required to offer a CMR to all beneficiaries, regardless of setting, in the event the beneficiary is cognitively impaired and cannot make decisions regarding his or her medical needs, we recommend that the pharmacist or qualified provider reach out to the beneficiary's prescriber, caregiver, or other authorized individual, such as the resident's health care proxy or legal guardian, to take part in the beneficiary's CMR. However, in the event the MTM provider is unable to identify another individual who is able to participate in the CMR, a CMR cannot be performed, but sponsors are required to perform TMRs at least quarterly with follow-up interventions when necessary and to perform prescriber interventions.

If asked, plan sponsors should be able to present documentation or a rationale for these determinations.

Beneficiaries in LTC Settings

In general, sponsors may utilize in-house resources or make arrangements with other resources (such as PBMs, MTM vendors, or individual pharmacists or other qualified providers) to provide MTM services and administer their MTM program to targeted beneficiaries.

LTC consultant pharmacists may be a valuable resource for the delivery of CMRs to targeted beneficiaries in LTC settings. Also, the potential overlap between the monthly drug regimen reviews (DRR) required in LTC and Part D MTM reviews could possibly result in conflicting recommendations. To maximize efficient use of healthcare resources, we encourage plan sponsors to consider making arrangements that include the LTC consultant pharmacist in conducting Part D MTM services for targeted beneficiaries in LTC. Such arrangements could include direct contracts between the sponsor and consultant pharmacists (or their intermediaries), or indirect contracts between the sponsor's MTM vendor or PBM and LTC consultant pharmacists (or their intermediaries).

We recommend that plan sponsors coordinate with LTC consultant pharmacists to determine if a beneficiary in the LTC setting is cognitively impaired and cannot accept the offer to participate in a CMR. Also, we recommend that when a targeted beneficiary moves to an LTC facility, Part D plan sponsors should identify the appropriate contact for each beneficiary, which could be the prescriber, caregiver, or authorized representative. Alternatively, sponsors could include this requirement in any arrangements that may be made with the LTC consultant pharmacist in the conduct of Part D MTM services.

² The Patient-Centered Primary Care Collaborative (PCPCC). The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes. 2010. Accessed March 19, 2012 at: <http://www.pcpcc.net/files/medmanagement.pdf>.

Instructions for Implementing the Standardized Format

An individualized, written summary in CMS' standardized format must be provided following each CMR. This applies whether the CMR is provided to the beneficiary, or to the beneficiary's prescriber, caregiver, or other authorized representative who may take part in the CMR if the beneficiary cannot participate. The standardized format with detailed instructions for implementation, and frequently asked questions are posted on the CMS MTM web page at www.cms.gov > Medicare > Prescription Drug Coverage Contracting > Medication Therapy Management (<http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/MTM.html>). The implementation instructions include the standardized format; document, page, and field specifications; delivery requirements and additional guidance; a completed sample; and a Spanish version. Part D sponsors must begin using the standardized format no later than January 1, 2013. The provision of the written summary in the standardized format requires certain minimum service levels for the CMR, which include discussion of the beneficiary's concerns with their drug therapy, collection of the purpose and instructions for using their medications, review of a beneficiary's medications including prescription, non-prescription drugs and supplements to aid in assessing medication therapy, and engaging beneficiaries in management of their drug therapy.

Targeted Medication Review (TMR)

For ongoing monitoring, sponsors are required to perform TMRs for all beneficiaries enrolled in the MTM program with follow-up interventions when necessary. The TMRs should occur at least quarterly to address specific or potential medication-related problems, and in particular, to assess medication use, to monitor whether any unresolved issues need attention, to determine if new drug therapy problems have arisen, or assess 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 for the beneficiary and/or their prescriber. These assessments could be person-to-person or system generated. The follow-up interventions with the beneficiaries should be person-to-person, if possible, but may be delivered via the mail or other means. Sponsors may determine how to tailor the follow-up interventions based on the specific needs or medication use issues of the beneficiary.

Sponsors may also offer follow-up interventions to the beneficiaries' prescribers to resolve medication-related problems or other opportunities to optimize the targeted beneficiaries' medication use. These prescriber consultations may be passive (e.g., faxed or mailed) or interactive when determined necessary.

Therefore, while the follow-up intervention that results from a TMR may be person-to-person, the TMR is distinct from a CMR because it is focused on specific actual or potential medication-related problems, and a CMR is a comprehensive, real-time, interactive medication review and consultation with the beneficiary to assess their medication use for the presence of medication-related problems and results in the creation of a written summary in CMS' standardized format.

Beneficiary Awareness

Sponsors are encouraged to increase beneficiaries' awareness about their MTM program and to promote the value of MTM services to beneficiaries. Sponsors should ensure that their customer service representatives and staff are familiar with the plans' MTM program. Starting in 2013, sponsors are required to have information on their website about their MTM program. Customer service and the website should provide at a minimum:

- The plan's MTM eligibility requirements,
- Who to contact for more information, and
- A high level summary of services offered as part of the MTM program.

Part D sponsors are also encouraged to post a blank Personal Medication List from the CMR standardized format on their website or provide information to beneficiaries about how to obtain a blank copy.

Outcomes Measurement

Sponsors are expected to have a process in place to measure, analyze, and report the outcomes of their MTM programs, whether or not goals of therapy have been reached; capture drug therapy recommendations and resolutions made as a result of the MTM recommendations; and to capture beneficiary satisfaction with MTM services, providers, and outcomes. A recommendation is defined as a suggestion to take a specific course of action related to the beneficiary's drug therapy.

- Examples of drug therapy problem recommendations made as a result of MTM services include, but are not limited to:
 - Needs additional therapy;
 - Unnecessary drug therapy;
 - Dosage too high;
 - Dosage too low;
 - More effective drug available;
 - Adverse drug reaction;
 - Medication Non-compliance/Non-adherence).
- Examples of drug therapy problem resolutions made as a result of MTM recommendations include, but are not limited to:
 - Initiate drug;
 - Change drug (such as product in different therapeutic class, dose, dosage form, quantity, or interval);
 - Discontinue or substitute drug (such as discontinue drug, generic substitution, therapeutic substitution, or formulary substitution);
 - Medication compliance/Adherence).

Sponsors are also encouraged to leverage effective MTM to improve safety (e.g., increase adherence to medications, reduce the use of high risk medications, and optimize diabetes

treatment), to help address issues of overutilization, and to use the monthly reports on the Part D Patient Safety Analysis website to help identify beneficiaries for whom targeted MTM interventions may be beneficial and achieve better outcomes.

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 MTM Program module, please contact the HPMS Help Desk at 1-800-220-2028.

Attachment 1

Contract Year 2013 Medication Therapy Management Program Enter/Edit Template

- This template serves as a guide to the information that must be entered in the Health Plan Management System (HPMS) Medication Therapy Management (MTM) Program Submission module. Refer to the HPMS CY 2013 MTM Program User's Guide User's Manual, available for download through the CY 2013 MTM Program Submission module in HPMS under Documentation, for more specific instructions and Enter/Edit page screen shots.
- Note: There are entry edits in place. For example, 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 MTM program, 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 MTM Program:

MTM program offered to:

(Select one)

- Only enrollees who meet the specified targeting criteria per CMS requirements
- Expanded eligibility: Enrollees who meet the specified targeting criteria per CMS requirements and enrollees who meet other plan-specific targeting criteria

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) [Note: Must select at least five out of the nine distinct core chronic diseases.]

| | |
|---|--|
| CORE: Alzheimer's Disease | CORE: Bone Disease-Arthritis-Osteoarthritis |
| CORE: Bone Disease-Arthritis-Osteoporosis | CORE: Bone Disease-Arthritis-Rheumatoid Arthritis |
| CORE: Chronic Heart Failure (CHF) | CORE: Diabetes |
| CORE: Dyslipidemia | CORE: End-Stage Renal Disease (ESRD) |
| CORE: Hypertension | CORE: Mental Health-Bipolar Disorder |
| CORE: Mental Health-Chronic/ Disabling Mental Health Conditions | CORE: Mental Health-Depression |
| CORE: Mental Health-Schizophrenia | CORE: Respiratory Disease-Asthma |
| CORE: Respiratory Disease-Chronic Lung Disorders | CORE: Respiratory Disease-Chronic Obstructive Pulmonary Disease (COPD) |
| Anemia | Anticoagulation |
| Atrial Fibrillation | Autoimmune Disorders |
| Benign Prostatic Hyperplasia (BPH) | Cancer |
| Cardiovascular Disorders | Cerebrovascular Disease |
| Chronic Alcohol and Other Drug Dependence | Chronic Noncancer Pain |
| Dementia | End-Stage Liver Disease |
| Acid / Reflux / Ulcers | Hepatitis C |
| HIV/AIDS | Multiple Sclerosis |
| Neurologic Disorders | Parkinson's Disease |
| Severe Hematologic Disorders | Stroke |
| 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**
- Specific Part D drug classes apply (Select all that apply)

| | | | |
|--------------------------|---|--------------------------|---|
| <input type="checkbox"/> | ACE Inhibitors | <input type="checkbox"/> | Alpha Blockers |
| <input type="checkbox"/> | Angiotensin II Receptor Blockers (ARBs) | <input type="checkbox"/> | Antiarrhythmics |
| <input type="checkbox"/> | Anticoagulants | <input type="checkbox"/> | Anticonvulsants |
| <input type="checkbox"/> | Antidepressants | <input type="checkbox"/> | Antiemetics |
| <input type="checkbox"/> | Antihyperlipidemics | <input type="checkbox"/> | Antihypertensives |
| <input type="checkbox"/> | Antineoplastics | <input type="checkbox"/> | Antiplatelets |
| <input type="checkbox"/> | Antipsychotics | <input type="checkbox"/> | Antiretroviral Therapy |
| <input type="checkbox"/> | Beta Blockers | <input type="checkbox"/> | Bisphosphonates |
| <input type="checkbox"/> | Bronchodilators | <input type="checkbox"/> | Calcium Channel Blockers |
| <input type="checkbox"/> | Disease-Modifying Anti-Rheumatic Drugs (DMARDs) | <input type="checkbox"/> | Diuretics |
| <input type="checkbox"/> | Inhaled Corticosteroids | <input type="checkbox"/> | Insulins |
| <input type="checkbox"/> | Interferons | <input type="checkbox"/> | Oral Hypoglycemics |
| <input type="checkbox"/> | Proton Pump Inhibitors | <input type="checkbox"/> | Selective Serotonin Reuptake Inhibitors (SSRIs) |
| <input type="checkbox"/> | Tumor Necrosis Factors (TNFs) | <input type="checkbox"/> | Other: |
| <input type="checkbox"/> | Other: | <input type="checkbox"/> | Other: |
| <input type="checkbox"/> | Other: | <input type="checkbox"/> | Other: |

- 3) Incurred Cost for Covered Part D Drugs:
- a) Provide description of the analytical procedure used to determine if the total annual cost of a beneficiary's covered Part D drugs is likely to equal or exceed the specified annual cost threshold. When selecting "Other" or "Formula," include the specific thresholds or formula. (Select all that apply)
- Specific Threshold and Frequency
- Incurred one-fourth of specified annual cost threshold in previous three months
- Incurred one-twelfth of specified annual cost threshold in previous month
- Incurred specified annual cost threshold in 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
- Reconciled medication list due to transition of care
- Other:

C. Enrollment

Opt-out only [Automatically selected-cannot be changed]

D. Interventions

Recipient of interventions:

(Select all that apply)

- Beneficiary [Automatically selected-cannot be changed]
- Prescriber [Automatically selected-cannot be changed]
- Caregiver
- Pharmacy/Pharmacist(s)
- Other:

Specific beneficiary interventions:

(Select all that apply)

Interactive, person-to-person, or telehealth Comprehensive Medication Review, annual [Automatically selected-cannot be changed]

Interactive, person-to-person consultation [Automatically selected-cannot be changed]

(Select all that apply)

- Face-to-face
- Phone
- Telehealth
- Other:

Materials delivered to beneficiary after the interactive, person-to-person CMR consultation [Automatically selected-cannot be changed]

(Select all that apply)

Individualized, written summary of CMR in CMS' standardized format (includes beneficiary cover letter, medication action plan, and personal medication list)

[Automatically selected-cannot be changed]

- Wallet card
- Medication guide
- Medication history
- Lab history
- Alternative language translations
- Other:

Delivery of individualized written summary of CMR in CMS' standardized format:

(Select all that apply)

- Mail
- Fax
- Email
- Web portal access
- Other:

- Targeted medication reviews, at least quarterly, with follow-up interventions when necessary
- [Automatically selected-cannot be changed]
- General education newsletter, beneficiary
- Refill reminder, beneficiary
- Referral: Disease Management
- Referral: Specialty Management
- Referral: Case Management
- Other:

Specific prescriber interventions:

(Select all that apply)

- 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
- Electronic data interchange consultation
- Other:
- General education newsletter, prescriber
- Patient Medication list
- Other:
- Other:
- Other:
- Other:

Specific caregiver interventions: [Only appears if selected 'Recipient of interventions: Caregiver']

(Select all that apply)

- Same as beneficiary interventions designated above
- Same as prescriber interventions designated above
- Other:
- Other:

Specific pharmacy/pharmacist(s) interventions: [Only appears if selected 'Recipient of interventions: Pharmacy/ Pharmacist(s)']

(Select all that apply)

- Same as beneficiary interventions designated above
- Same as prescriber interventions designated above
- Other:
- Other:

Specific other recipient interventions: [Only appears if selected 'Recipient of interventions: Other']

(Select all that apply)

- Other:
- Other:
- Other:
- Other:

(Provide a detailed description of how your program will provide the MTM interventions, including a description of the required MTM services (interventions, for both beneficiaries and prescribers; an annual comprehensive medication review, which includes an interactive, person-to-person or telehealth consultation and an individualized, written summary in CMS' standardized format; and quarterly targeted medication reviews with follow-up interventions when necessary) and any other value added MTM services provided)

[Text Box]

E. Resources

Provider of MTM services

(Select all that apply)

In-house staff

Pharmacist

Physician

Registered Nurse

Case Manager

Licensed Practical Nurse

Nurse Practitioner

Physician's Assistant

Other:

Outside personnel

PBM

Name of PBM:

Pharmacist

Physician

Registered Nurse

Licensed Practical Nurse

Nurse Practitioner

Physician's Assistant

Other:

Disease Management vendor

Name of vendor:

Pharmacist

Physician

Registered Nurse

Licensed Practical Nurse

Nurse Practitioner

Physician's Assistant

Other:

Medication Therapy Management vendor

Name of vendor:

In-house Pharmacist

Local Pharmacist

Physician

Registered Nurse

Licensed Practical Nurse

Nurse Practitioner

Physician's Assistant

Other:

Local pharmacists

Long-Term Care (LTC) consultant pharmacists

Hospital pharmacists

Physician

Registered Nurse

Licensed Practical Nurse

Nurse Practitioner

Physician's Assistant

Other:

Qualified Provider of Interactive, Person-to-Person CMR with written summaries
 (Select all that apply)

- Local pharmacist
- Long-Term Care (LTC) consultant pharmacist
- Plan Sponsor Pharmacist
- Plan Benefit Manager Pharmacist
- MTM Vendor Local Pharmacist
- MTM Vendor In-house Pharmacist
- Physician
- Registered Nurse
- Licensed Practical Nurse
- Nurse Practitioner
- Physician's Assistant
- 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 specific fee(s), billing method(s) and/or description 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* | |
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| \$00000.00 | Use drop Down Options* | |
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- *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.)

Part D Reporting Requirements. [Automatically selected-cannot be changed]

Drug-drug interactions measure

High risk medications (drugs to be avoided in elderly) measure

Diabetes medication dosing measure

Diabetes (suboptimal) treatment measure

Medication adherence measure (Proportion of Days Covered)

Medication persistence

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]

Attachment 2: Information that MUST be included with the MTM Program Submission

Targeting criteria for eligibility in the MTM program

1. General information:

- Designate who your MTM program is offered to:
 1. Only enrollees who meet the specified targeting criteria per CMS requirements, or
 2. Enrollees who meet the specified targeting criteria per CMS requirements and enrollees who meet other plan-specific targeting criteria (expanded criteria).
- Note: Whether based only on CMS' specifications or other expanded plan-specific targeting criteria, for reporting purposes, the beneficiaries must receive MTM services that at a minimum meet CMS' MTM program requirements.

2. Targeting Criterion #1: Multiple Chronic Diseases

- Provide the minimum number of distinct chronic diseases a beneficiary must have for eligibility in your MTM program. (Note: this minimum threshold is required to be 2 or 3.)
- Provide the specific name of each chronic disease included as part of your targeting criteria or if any chronic disease will be included. At a minimum, you must include at least five of the nine core chronic conditions.

Example 1: A beneficiary must have 2 or more chronic diseases, and beneficiaries with any chronic diseases will be targeted.

Example 2: A beneficiary must have 2 or more chronic diseases. Beneficiaries with at least 2 of the following chronic diseases will be targeted: Respiratory Disease-Asthma, Diabetes, Chronic Heart Failure, Dyslipidemia, or Hypertension.

Example 3: A beneficiary must have 3 or more chronic diseases. Beneficiaries with at least 3 of the following chronic diseases will be targeted: Respiratory Disease-Asthma, Respiratory Disease-COPD, Bone Disease-Arthritis-Rheumatoid Arthritis, Dyslipidemia, Hypertension, Diabetes, Mental Health-Depression, Chronic Noncancer Pain, or HIV/AIDS.

3. Targeting Criterion #2: Multiple Covered Part D Drugs

- Provide the minimum number of covered Part D drugs that a beneficiary must have filled for eligibility in your MTM program. (Note: this minimum threshold is required to be any number ≥ 2 and ≤ 8 .)
- Provide the type of covered Part D drugs that applies: any Part D drug, chronic/maintenance drugs, or specific Part D drug classes.

Example 1: 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.

4. Targeting Criterion #3: Incurred Cost for Covered Part D Drugs
 - Provide the analytical procedure used to determine if a beneficiary is likely to incur annual costs greater than or equal to \$3,144 for eligibility in your MTM program.
 - Provide the specific thresholds per time, the formula, or describe in detail the predictive model used to identify beneficiaries who are likely to incur this annual cost threshold. Sponsors may enter additional details in the Additional Information section if needed.
 - Note: Sponsors should consider methods to identify if a beneficiary is likely to incur this annual cost threshold through methods that not only review historical claims, but also target beneficiaries prospectively. Therefore, programs that only target beneficiaries who have incurred the annual cost threshold in the previous 12 months will not be accepted.

Example: Incurred one-fourth of specified annual cost threshold in previous quarter or incurred specified annual cost threshold in previous 12 months.

Targeting

1. Provide the frequency that your MTM program identifies beneficiaries, which must be at least quarterly. For example, daily, weekly, monthly, or quarterly targeting frequencies would meet this requirement.
2. Provide the type(s) of data you evaluate to target eligible beneficiaries.

Enrollment/ Disenrollment

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

Interventions

1. Recipient of MTM interventions.
 - Provide the recipient of the MTM interventions. This will automatically default to beneficiary and prescriber. Other recipients may be designated, such as caregiver, pharmacist, or others.
2. Specific beneficiary interventions.
 - Provide the specific beneficiary interventions. This will automatically default to specific selections to indicate that your MTM program will offer the required minimum MTM services to each targeted beneficiary regardless of setting (annual CMR with written summaries in CMS' standardized format and quarterly TMRs).
 - Provide the method(s) of delivery for the interactive, person-to-person consultation.
 - Note: Mail-based or other non-interactive interventions may be part of your overall MTM program, but do not satisfy the interactive CMR requirement and, therefore, should not be provided for this selection.

However, sponsors may provide additional mail based interventions and should describe these interventions in the detailed description of their interventions.

- Provide the materials delivered to the beneficiary after the CMR. This will automatically default to an individualized written summary in CMS' standardized format. Indicate if you provide any additional supplemental materials.
 - Provide the method(s) of delivery of the written summary in CMS' standardized format.
3. Provide the specific prescriber interventions.
 - Provide the specific prescriber interventions. This will automatically default to prescriber interventions to resolve medication-related problems or optimize therapy.
 - Provide the type(s) of prescriber consultations offered.
 4. Intervention description.
 - Provide a **detailed** description of how your program will provide the MTM interventions, including a description of the required MTM services (interventions, for both beneficiaries and prescribers; an annual CMR, which includes an interactive, person-to-person or telehealth consultation and an individualized, written summary in CMS' standardized format; and quarterly targeted medication reviews with follow-up interventions when necessary) and any other value added MTM services offered.
 - Note: Submissions that do not include detailed descriptions of what interventions are in place to meet each the MTM requirements will be found deficient. If sponsors require additional space, the two Additional Information text boxes may be used.

Resources

1. Provide the type(s) of personnel that will be providing your program's MTM services such as in-house staff or outside personnel (including name(s)).
2. Provide the qualified provider(s) that will be providing your program's MTM services.
3. Provide the specific qualified provider(s) who provide the CMRs for your MTM program.

Fees

1. Designate how fees will be established for your MTM program if using outside personnel. If establishing fees for pharmacists or others, provide the amount of fee respective to MTM program management and the fee paid for the provider of the MTM services.
2. 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.

3. 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 must be reported.
 - Provide the specific fee(s), billing method(s) such as per minute or per service, and an optional description.

Outcomes Measured

1. Provide the methods of documenting and measuring outcomes or your MTM program.