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TO: All Part D Sponsors

FROM: Amy K. Larrick, Acting Director,
Medicare Drug Benefit and C & D Data Group

SUBJECT: CY 2016 Medication Therapy Management Program Guidance and Submission
Instructions

DATE: April 7, 2015

This memorandum provides guidance to Part D sponsors regarding contract year (CY) 2016 Medication Therapy Management (MTM) programs including:

- Important dates for the CY 2016 MTM Program submission module will be released and when submissions are due;
- Changes to the CY 2016 module compared to last year's module;
- The requirements for establishing MTM programs for CY 2016;
- Instructions for submitting change requests for approved programs; and
- Information to assist sponsors with their submissions.

I. Important Dates and Information for 2016 MTM Program Submissions

The CY 2016 MTM program submission deadline is **May 4, 2015** for all Part D sponsors*.

Action	Key Date*
Release of the CY 2016 MTM Program submission module in HPMS	April 20, 2015
2016 MTM Program Submission Deadline	May 4, 2015, 11:59pm PDT.

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

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 2016 Part D requirements and expectations are described later in this memo.

These requirements do not apply to MA Private Fee for Service (MA-PFFS) organizations or PACE organizations. However, considering that 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. MA-PFFS organizations must follow the same annual submission and approval process when establishing a program. These requirements do apply to Employer Group Waiver Plans (EGWPs).

The CY 2016 MTM program description 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. MTM programs are established and approved at the contract level. A technical user’s manual titled, HPMS CY 2016 MTM Program User’s Guide, is available for download through the CY 2016 MTM Program Submission module under Documentation. Sponsors should refer to the user’s manual while navigating through the MTM Program submission module and performing Plan functions. Attachment 1 contains instructions regarding the information that must be included in the submission.

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 approval. Communications will be sent via email to the 2016 HPMS MTM Program Main Contact and the 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.

II. Changes to the CY 2016 module compared to the CY 2015 module

Each year, CMS reviews the HPMS MTM Program submission module to identify improvements that can be made to make the process clearer and more efficient. For the CY 2016 module, CMS added additional selections in the Provider of MTM Services section under Provider of MTM Services and Qualified Provider of Interactive, Person-to-Person Comprehensive Medication Review (CMR) with written summaries sections and updated the CY 2016 annual cost threshold amount.

- Under the Provider of MTM Services, sponsors will now be able to select Pharmacy Intern Under Direct Supervision of a Pharmacist or Pharmacy Technician, if applicable.
- Similarly, under Qualified Provider of Interactive, Person-to-Person CMR with written summaries, sponsors will now be able to select Disease Management

Pharmacist and Pharmacy Intern Under Direct Supervision of a Pharmacist, if applicable.

- The 2016 MTM program annual cost threshold is \$3,507.

III. 2016 Medication Therapy Management (MTM) Program Requirements

In general, the requirements and guidance for Part D MTM programs are unchanged from CY 2015. The 2016 MTM program annual cost threshold increased to \$3,507.

Per section 423.153(d), 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 which results in the creation of a written summary in CMS' standardized format, and frequent monitoring and follow-up of the beneficiary's 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. Once a beneficiary has enrolled in the MTM program, sponsors should begin performing Targeted Medication Reviews (TMRs) at least quarterly with follow-up interventions as necessary, begin providing prescriber interventions, and offer the annual CMR in a timely manner. 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. 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 year. Part D sponsors are also expected to promote continuity of care by performing an analysis at the end of the year to identify current MTM program participants who will again meet the eligibility criteria for the next program year for the same contract. This targeting could be done to auto-enroll eligible beneficiaries in the MTM program early in the next program year in order to prevent interruption of MTM interventions. To determine if the beneficiary meets the targeting criteria for the new program year, sponsors may use claims from the previous year or claims from the current year to base these projections.

Targeted Beneficiaries

Targeted beneficiaries for the MTM program are enrollees who meet all of the following criteria of the sponsor's Part D plan. 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 automatically 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 should include a condition from 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 annual costs for covered Part D drugs greater than or equal to the specified MTM cost threshold.

The 2015 MTM program annual cost threshold is \$3,138. The MTM program annual cost threshold is updated for 2016 using the annual percentage increase of 11.76%, as specified in the Calendar Year (CY) 2016 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter. Therefore, the 2016 MTM program annual cost threshold is \$3,507.

The drug costs 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 for MTM program eligibility include the ingredient cost, dispensing fee, sales tax, and vaccine administration fee, if applicable. This projection may be based on claims within the program year or based on historical claims from the previous year.

Sponsors are encouraged to optimize their programs, including their targeting criteria, to offer MTM to beneficiaries who will benefit the most from these services. We remind sponsors that the CMS eligibility targeting requirements are established as the minimum threshold. Sponsors may also offer MTM services to an expanded population of beneficiaries who do not meet the eligibility criteria under section 423.153(d). Sponsors should not restrict their MTM eligibility criteria to limit the number and percent of beneficiaries who qualify for these programs.

Sponsors are also encouraged, but not required, to offer MTM services or other interventions to beneficiaries who fill at least one prescription for an anti-hypertensive medication to support the Millions Hearts™ Initiatives to control high blood pressure and improve access and adherence to these medications.

In addition, overutilization of opioids is a significant concern, especially in the treatment of patients with chronic noncancer pain. Therefore we encourage, but do not require, sponsors to also offer MTM services to beneficiaries who meet the sponsor's internal criteria for retrospective identification of opioid overutilization, but do not otherwise qualify for MTM. These beneficiaries may benefit from MTM services including the CMR, targeted medication reviews, and interventions with their prescribers.

CMS considers MTM program services provided to targeted beneficiaries as an administrative cost (included in the plan bid), incident to appropriate drug therapy, and not an additional benefit. An MTM program is based on the contract year. The plan's bid should take into account MTM costs for the applicable contract year, as MTM programs can change from year to year.

However, the CMS eligibility targeting requirements are established as the minimum threshold. Therefore, we believe that as part of their broader efforts with respect to drug utilization management and quality assurance, sponsors may also elect to offer MTM services to an expanded population of beneficiaries who do not meet the eligibility criteria under section 423.153(d). Sponsors may incorporate these additional costs of providing MTM services to an expanded population in the administrative costs in their bids.

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 CMR with written summaries in CMS' standardized format.
 - 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.
 - 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 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. 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 in CMS' standardized format.

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 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 enrolled in the MTM program, regardless of setting, in the event the beneficiary is cognitively impaired or otherwise unable to participate, 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. This applies to beneficiaries in any setting and is not limited to beneficiaries in long term care (LTC). 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.

Optimizing the Delivery of MTM in Long Term Care Settings

Sponsors must offer a CMR to all beneficiaries enrolled in their MTM program at least annually, and this includes enrollees who are in LTC settings.

MTM and CMRs for beneficiaries in LTC provide new opportunities to serve this vulnerable population and improve their medication use and quality of care. While there is some overlap between the monthly drug regimen reviews (DRR) required in LTC and Part D MTM reviews, a CMR must meet the CMS service-level definition. For each CMR, the pharmacist or other qualified provider must conduct 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). It must be performed in real-time with the beneficiary (or the beneficiary's caregiver or other authorized representative who may take part in the CMR if the beneficiary cannot participate). It must provide a written summary of the results of the review in the CMS standardized format to the individual. The summary includes a personalized medication action plan and medication list for the beneficiary and/or their caregiver or authorized representative.

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 April 14, 2014 at: http://www.pharmacist.com/sites/default/files/files/core_elements_of_an_mtm_practice.pdf.

² The Patient-Centered Primary Care Collaborative (PCPCC). The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes. 2012. Accessed April 14, 2014 at: <http://www.pcpcc.org/sites/default/files/media/medmanagement.pdf>

There may be different issues and opportunities to improve medication use through MTM for beneficiaries in the LTC setting compared to ambulatory settings. In the ambulatory setting, goals include ensuring the beneficiary is on the right drug and dose and improving medication adherence. In LTC, adherence is less of an issue, and MTM can be used to identify overuse, medications without a clear indication, suboptimal dosing, and polypharmacy. Also, MTM could be used as an opportunity to align medication use with the beneficiary's goals and wishes in addition to the care team's.

Sponsors should ensure that their policies and procedures for offering and delivering CMRs, as established by CMS requirements, are effective for beneficiaries taking into consideration how to reach the beneficiary according to their setting and needs. Regardless of setting, sponsors are expected to use more than one approach when possible to reach all eligible targeted beneficiaries (or their authorized representatives, if the beneficiary is cognitively impaired or otherwise unable to participate) to offer MTM services versus only reaching out via passive offers. In the LTC setting, a greater risk of both physical and cognitive issues may impact the beneficiary's ability to conduct a phone interview. Sponsors should consider using qualified providers to perform the CMR who have experience engaging beneficiaries and prescribers in the LTC setting, such as involvement of a pharmacist who has a relationship with the LTC facility. To avoid conflicting recommendations, the MTM provider should coordinate the recommendations for drug therapy changes as a result of an MTM encounter with the beneficiary's treating physician and healthcare team at the facility, their caregiver or authorized representative, when applicable, and consultant pharmacist. Additional consideration could be given to coordinate MTM activities with the care plan meeting to assess current treatment regimens. The beneficiary or authorized representative should be invited to these meetings, and often the facility has an understanding of which beneficiaries are interested in being involved in their care and which defer to their authorized representatives.

In the event the beneficiary is unable to accept the offer to participate, the pharmacist or qualified provider may perform the CMR with the beneficiary's caregiver, other authorized individual, such as the beneficiary's health care proxy or legal guardian, or prescriber. To the extent possible, preference should be given to involving the beneficiary's caregiver to further engage them in the management of the beneficiary's medications. Regardless of cognitive status, many LTC residents may prefer to involve their authorized representative or caregiver in the CMR, and this should be considered when serving this population. Furthermore, beneficiaries in LTC are less likely to self-administer their own medications and cognition can vary on any given day even if it was determined that the beneficiary is not severely cognitively impaired. The nursing staff, including but not limited to the Director of Nursing, may be a valuable asset to ascertain information about a beneficiary's functional status, cognitive status, and medications, as well as caregiver(s) or authorized representative(s). If asked, plan sponsors should be able to present documentation or a rationale for determining a beneficiary to be cognitively impaired or otherwise unable to participate in the CMR.

We recommend that when a targeted beneficiary moves to a LTC facility, Part D plan sponsors should identify the appropriate contact for each beneficiary. This contact could be the authorized representative, caregiver, or prescriber. Sponsors, or their MTM providers, could contact the admissions coordinator, MDS coordinator, Director of Nursing, or other appropriate facility staff person to ascertain if an authorized representative has been designated in the beneficiary's medical record or chart. Sponsors are encouraged to develop processes and procedures to contact the facility in the least burdensome manner to request assistance from the facility to identify beneficiaries who are not cognitively impaired and may be receptive to receiving a CMR, and beneficiaries who have a health care proxy. In the event that the definition of authorized representative differs by State or in settings other than LTC, we defer to State law.

One tool that could be used in nursing homes to identify if a beneficiary is cognitively impaired or able to participate in the CMR is the Brief Interview of Mental Status (BIMS) in the Minimum Data Set 3.0. Currently, Surveyors determine whether a resident is "interviewable." Residents may be identified as "interviewable" if they have a BIMS score of 8-15; at a score of 0-7 or 99, the resident may be identified as a "Family Interview Candidate" or as needing some other authorized representative.³ A similar process could be used by MTM providers to evaluate if a beneficiary is "interviewable" and can participate in the CMR. The following algorithm could be applied using MDS 3.0.

IF

1. MDS item C0500 [Brief Interview for Mental Status (BIMS) Summary Score] = 8-15

BIMS Summary Scoring

- 13 - 15: Cognitively intact
- 8 - 12: Moderately impaired
- 0 -7: Severe impairment

AND

2. MDS Item B0700 ("Makes Self Understood") = 0 or 1

"Makes Self Understood" Scoring

- 0 = Understood
- 1 = Usually understood
- 2 = Sometimes understood
- 3 = Rarely/never understood

AND

3. MDS Item B0800 ("Ability to Understand Others") = 0 or 1

"Ability to Understand Others" Scoring

- 0 = Understands
- 1 = Usually understands

³ Memo from the Director, Survey and Certification Group. September 27, 2012. *Advance Copy of Interim Guidance - Revisions to State Operations Manual (SOM), Appendix P-Traditional Survey Protocol for Long Term Care (LTC) Facilities and Chapter 9/Exhibits including Survey Forms 672, 802, 802S and 802P.*

- 2 = Sometimes understands
- 3 = Rarely/never understands

THEN: The resident should be considered able to receive a CMR.

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. 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 must occur at least quarterly upon enrollment in the MTM program and may address specific or potential medication-related problems. In particular, TMRs may be performed 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.

Coordination of Care

MTM can be used to promote the coordination of care. Beneficiaries should be encouraged to complete their annual CMR prior to their annual wellness visit, and to take their standardized medication action plan and personal medication list from their CMR to their annual wellness visit or any medical encounter (primary care physician or specialist visit, hospital admission, etc.). This summary can serve as a valuable tool to share information across providers and help reduce duplicate therapy and drug-drug interactions. The *Medicare & You Handbook* also encourages beneficiaries to schedule their CMR prior to their yearly wellness visit. Part D sponsors are encouraged to communicate this recommendation to beneficiaries when notifying beneficiaries of their enrollment in the MTM program and when offering or scheduling CMRs, and to explore other opportunities to use MTM to better coordinate care. For example, CMRs may be beneficial after a transition in care or after a hospitalization.

Plan sponsors are encouraged to adopt standardized health information technology (HIT) for documentation of MTM services. Structured, universal codes (e.g., SNOMED CT) are available for clinical coding of MTM services delivered to beneficiaries, such as findings, recommendations, and outcomes. The use of standardized coding systems improves the efficiency of documentation by the MTM provider, supports consistent clinical record keeping, facilitates the transfer of information between health care providers and beneficiaries, and will allow better collection and analysis of the impact of MTM services on beneficiaries' care. Combining standardized coding systems and industry-supported templates (e.g., NCPDP/HL7 MTM Template CDA) will also enable sponsors to update and print summaries of CMRs in a standardized format based on standard elements in databases and EHRs rather than manipulating free-form text documents.

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.

In accordance with the Medicare Marketing Guidelines, Part D sponsors are expected to include on their websites a separate section or page about MTM programs, written in plain language for beneficiaries including:

- Part D sponsor’s specific MTM program eligibility requirements,
- A statement informing beneficiaries who to contact at the Part D sponsor for more information, with customer service personnel prepared to answer questions about the MTM program,
- High level summary of services offered as part of the MTM program,
- A statement explaining the purpose and benefits of MTM, and that this is a free service for eligible beneficiaries,
- A description of how the beneficiary will be notified by the Part D sponsor that they are eligible and enrolled in the MTM program,
- Statements on how they will be contacted and offered services by the Part D sponsor, including the comprehensive medication review and targeted medication reviews, and a description of how the reviews are conducted and delivered, including time commitments and materials beneficiaries will receive,
- A statement on how the beneficiary may obtain MTM service documents, including a blank copy of the Personal Medication List posted on the website, and
- A statement clarifying that these programs are not considered a benefit.

If possible, this page should be accessible by clicking through a maximum of two links.

Increasing font sizes and using lay language will help beneficiaries to read and understand the content of the MTM webpage.

The Medicare Plan Finder (MPF) will continue to include an MTM (“Manage Drugs”) tab on the “Your Plan Details” page, which will allow beneficiaries to view the plan’s MTM program eligibility information and a link to the plan’s MTM program web page. Sponsors should ensure that the MTM program web page URL reported with their program submission in HPMS is accurate and functioning. Sponsors may be subject to compliance actions if the MTM web page URL is not functioning or does not meet the guidelines.

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.

IV. Requests to Make Changes to an Approved MTM Program

All changes to a Part D sponsor's approved MTM program for a given contract year must be submitted to CMS for review and approval prior to the implementation of the changes.

Policy

1. Part D sponsors may make *positive* changes to the targeting criteria to make the eligibility more inclusive or to increase the number of beneficiaries eligible to receive Part D MTM services, including:
 - Decreasing the minimum number of multiple chronic diseases,
 - Expanding the list of specific chronic diseases that apply,
 - Decreasing the minimum number of multiple covered Part D drugs,
 - 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 including changes to:
 - Frequency of identification to increase or promote ease of beneficiary participation,

- Expand the levels of intervention or services provided to targeted beneficiaries,
 - Methods of documenting and measuring outcomes,
 - The qualified provider of MTM services,
 - Any fee schedules established for pharmacists and other MTM providers if using outside personnel. CMS will request that Part D sponsors disclose the newly established fees for outside personnel.
3. Part D sponsors *may not* make any negative changes to their MTM program, including changes that:
- Promote discriminatory or exclusionary practices,
 - Decrease the number of enrollees eligible for MTM services,
 - Lower quality or robustness of MTM services.

Submission Process

The HPMS MTM Program Submission module also allows sponsors to submit MTM program change requests during four Update Windows. Please refer to the technical user manual available in HPMS.

Sponsors may request changes to their CMS-approved program during any the following Update Cycle windows:

- September 1 - September 10, prior to the contract year (i.e., before effective date of the approved MTM program),
- March 1 - March 10, within the contract year (i.e., after implementation date of approved MTM program),
- June 1 - June 10, within the contract year, and,
- September 1 - September 10, within the contract year.

The MTM Program Module submission gates are automatically open during these Update Cycle windows. Sponsors should (1) directly edit the program description in the applicable data entry page(s) and (2) enter information in the Change Request Form Description field(s) to justify the changes to the applicable data entry page(s). In addition, sponsors must check the attestation, "I attest that the following change(s) 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." on the Verify Submission page.

Part D sponsors will receive an email correspondence regarding the approval of the change. Depending upon the volume of requests, plans should expect a response within 30 days. The changes should be implemented within a reasonable time following approval. Sponsors may not adjust their bids based on requested changes to their CMS-approved MTM program.

We encourage sponsors to submit changes during the Update Cycle windows. The submission gates will only be reopened outside of the Update Cycle windows if your

contract requires resubmission of your MTM program to correct deficiencies. If your contract needs to submit your program outside of these windows, please email your request to have the submission gate opened in HPMS to **partd_mtm@cms.hhs.gov**. It is essential to include the contract ID(s) in the email request and the applicable contract year.

Attachment 1: Information that MUST be included with the MTM Program Submission

Targeting criteria for eligibility in the MTM program

1. General information:

- MTM Program Web Page URL (one per contract)
- 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: The selections and descriptions should generally apply to your MTM program that meets CMS – Part D requirements pursuant to §423.153(d) of the regulations. Use the Additional Information text boxes to describe your expanded MTM program, if applicable, and clearly designate when referring to expanded program criteria or offerings.

2. Targeting Criterion #1 per CMS requirements: 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 should include a condition within 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 per CMS requirements: 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 the total annual cost of a beneficiary's covered Part D drugs is likely to equal or exceed the specified annual cost threshold (\$3,507).
 - 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 (\$3,507) 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, pharmacy/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 all of the required MTM services **regardless of setting**, 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 additional 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. Four text boxes are now provided.**
 - ✓ Provide a detailed description of the MTM interventions your program will offer for both beneficiaries and prescribers.
 - ✓ Provide a detailed description of your MTM program's annual comprehensive medication review, including an interactive, person-to-person, or telehealth consultation and the provision of an individualized, written summary in CMS' standardized format.
 - ✓ Provide a detailed description of how your MTM program will perform targeted medication reviews, at least quarterly, with follow-up interventions when necessary.
 - ✓ Provide a detailed description of any other value added MTM services that your MTM program will offer (Optional).
 - 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. Selections with non-qualified providers will be found deficient.

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, Disease Management vendor, or MTM 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, Disease Management vendor, or MTM 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.
 - One fee table may be associated with all outside personnel, or different fees tables for each outside personnel.

Outcomes Measured

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