DEPARTMENT OF HEALTH & HUMAN SERVICES
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DATE: May 06, 2024

TO: All Prescription Drug Plans, Medicare Advantage – Prescription Drug Plans, and Medicare-Medicaid Plans

FROM: Vanessa S. Duran, Director
Medicare Drug Benefit and C & D Data Group

SUBJECT: Contract Year 2025 Part D Medication Therapy Management Program Guidance and Submission Instructions

This memorandum provides guidance to Part D sponsors regarding contract year (CY) 2025 Part D Medication Therapy Management (MTM) programs including:

- Important dates for the release of the CY 2025 MTM Program submission module and when submissions and attestations are due;
- Summary of the requirements for establishing MTM programs for CY 2025;
- Information to assist sponsors with their submissions and attestations;
- Changes to the CY 2025 module compared to the CY 2024 module; and
- Instructions for submitting change requests for approved programs.

I. Important Dates and Information for 2025 MTM Program Submissions and Attestations

The CY 2025 MTM program submission deadline is **June 5, 2024,** for all Part D sponsors.[1]

Action	Key Date
Release of the CY 2025 MTM Program submission module in the Health Plan Management System (HPMS)	May 22, 2024
2025 MTM Program Submission Deadline	June 5, 2024, 11:59pm PDT
2025 MTM Program Attestation Deadline	June 20, 2024, 11:59pm PDT

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

A technical document titled "HPMS CY 2025 MTM Program User Manual" will be available in early May for download through the CY 2025 MTM Program Submission module under Documentation in HPMS.

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 through the HPMS. CMS evaluates each program description to verify that it meets the current minimum requirements for the program year as established in 42 CFR § 423.153(d). The CY 2025 Part D requirements and expectations are summarized in this memorandum; for more detailed information about these requirements, see 42 CFR § 423.153(d) and applicable final regulations published in the Federal Register, including the final rule (89 FR 30448)[1] issued on April 4, 2024.

These requirements do apply to Employer Group Waiver Plans (EGWPs). 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 that choose to establish an MTM program must follow the same annual submissionand approval process.

II. Summary of 2025 Medication Therapy Management (MTM) Program Requirements

Per 42 CFR § 423.153(d), Part D sponsors must establish 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. Part D sponsors are required to offer each beneficiary enrolled in the MTM program the same minimum level of MTM services as specified in 42 CFR § 423.153(d)(1)(vii).

[1] The April 2024 final rule is available at: https://www.federalregister.gov/public-inspection/2024-07105/medicare-program-medicare-advantage-and-the-medicare-prescription-drug-benefit-program-for-contract

Recent Changes

The April 2024 final rule implements changes to the MTM program requirements beginning January 1, 2025. The final rule makes the following changes to the MTM program eligibility criteria:

1. Codifying the nine core chronic diseases currently identified in guidance and adding HIV/AIDS, for a total of ten core chronic diseases that Part D sponsors must include in their targeting criteria to identify beneficiaries who have multiple chronic diseases and continuing to allow Part D sponsors to include additional chronic diseases;

2. Requiring Part D sponsors to include all Part D maintenance drugs in their targeting criteria to identify beneficiaries taking multiple Part D drugs, relying on information in a widely accepted, commercially or publicly available drug database to make such determinations and continuing to allow Part D sponsors to include all Part D drugs; and

3. Revising the methodology for calculating the cost threshold to be commensurate with the average annual cost of eight generic drugs ($1,623 in 2025).

In addition, CMS codified longstanding guidance that a beneficiary is unable to accept an offer to participate in the comprehensive medication review only when the beneficiary is cognitively impaired and other technical changes to clarify that the CMR must include a real-time interactive consultation that is conducted in person or via synchronous telehealth. These requirements are summarized further in this memorandum.

Targeted Beneficiaries

Targeted beneficiaries for the MTM program are enrollees who meet the characteristics of at least one of the following two groups ((1) and/or (2)) per 42 CFR § 423.153(d)(2):

1. A) 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 three 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 two or three.

   Sponsors must include all ten of the following core chronic diseases, as defined at 42 CFR § 423.153(d)(2)(iii), in their targeting criteria:

   - Alzheimer's disease;
   - Bone disease-arthritis (including osteoporosis, osteoarthritis, and rheumatoid arthritis);
   - Chronic congestive heart failure (CHF);
   - Diabetes;

- Dyslipidemia;
- End-stage renal disease (ESRD);
- Human immunodeficiency virus /acquired immunodeficiency syndrome (HIV/AIDS)
- Hypertension;
- Mental health (including depression, schizophrenia, bipolar disorder, and chronic/disabling mental health conditions).
- Respiratory disease (including asthma, chronic obstructive pulmonary disease (COPD), and chronic lung disorders).

Sponsors may include additional chronic diseases.

AND

B) Are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require as the minimum number of Part D drugs that a beneficiary must be taking for targeted enrollment. Sponsors may set this minimum threshold at any number equal to or between two and eight.

Pursuant to 42 CFR § 423.153(d)(2)(iv), in identifying the number of Part D drugs, sponsors must include all Part D maintenance drugs, relying on information in a widely accepted, commercially or publicly available drug database, such as Medi-Span or First Databank, to make such determinations, and may include all Part D drugs.

AND

C) Are likely to incur annual costs for covered Part D drugs greater than or equal to the specified MTM cost threshold.

Beginning January 1, 2025, per 42 CFR § 423.153(d)(2)(i)(C), the MTM cost threshold is set at the average annual cost of eight generic drugs, as defined at 42 CFR § 423.4, and determined using the prescription drug event (PDE) data specified at 42 CFR § 423.104(d)(2)(iv)(C). Based on analysis of 2023 PDE data, the MTM cost threshold will be $1,623 for 2025.

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 fees, sales tax, and vaccine administration fee,[2] if applicable, and include both plan paid amounts and enrollee cost sharing. This projection may be based on claims within the

[2] See the March 8, 2024 memorandum titled "2025 Prescription Drug Event File Layout Updates for all Part D Plan Sponsors, and Additional 2025 Changes to PDE Reporting for PACE Organizations". The description of the "Vaccine Administration Fee or Additional Dispensing Fee" was modified on both the 2025 PDE Inbound and Outbound File Layouts to conform to recently announced changes applied to the 2024 PDE File Layouts available at: https://www.csscoperations.com/internet/csscw3.nsf/DIDC/5STYLICW8P~ListServs~Prescription%20Drug%20Program%20(Part%20D).

program year or based on historical claims from the previous year.

2. Are at-risk beneficiaries (ARBs) as defined at 42 CFR § 423.100.

   All ARBs – that is, beneficiaries with an active coverage limitation under a drug management program (DMP), must be targeted for enrollment in MTM.

There may be some overlap between the populations that meet the eligibility criteria under (1) and (2), for example, a beneficiary who is an ARB under the plan's DMP (i.e., (2)) who also meets MTM criteria based on having multiple chronic diseases, taking multiple Part D drugs, and meeting or exceeding the cost threshold (i.e., (1)). Despite the possibility for overlap, sponsors must identify all targeted beneficiaries eligible for MTM and apply the same requirements for targeting regardless of whether the beneficiary meets the criteria under (1), (2), or both. Sponsors should not implement discriminatory exclusion criteria; if a beneficiary meets the eligibility criteria under group (1) and/or (2), the beneficiary should automatically be enrolled into the MTM program. See the technical HPMS User Guide for examples of targeting criteria submissions.

Sponsors are encouraged to optimize their MTM programs, including their targeting criteria, to offer MTM to beneficiaries who will benefit the most from these services. We remind sponsors that the CMS 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 42 CFR § 423.153(d) and may incorporate the additional costs of providing MTM services to an expanded population in the administrative costs in their bids MTM eligibility criteria should not be restricted to limit the number and percent of beneficiaries who qualify for these programs.

Sponsors are 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™ initiative to control high blood pressure and improve access and adherence to these medications. Also, equitable access to cancer screening and targeting the right treatments for cancer patients are top priorities under the goals of the Cancer Moonshot. Some cancer patients may be eligible for MTM based on meeting the eligibility criteria. We encourage Part D plans and MTM providers to seek opportunities to promote cancer screening where possible for MTM enrollees and to coordinate with specialty cancer programs to develop medication safety recommendations for cancer patients.

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. For the purposes of calculating the Medical Loss Ratio (MLR), MTM programs that comply with 42 CFR § 423.153(d) and are offered by Part D sponsors (including MA organizations that offer MA-PD plans (described in 42 CFR § 422.2420(a)(2)) are "quality improvement activities" (QIAs).[3]

[3] Pursuant to 42 CFR §§ 422.2430(a)(1)(ii) and (4)(i); 423.2430(a)(1)(ii) and (4)(i), MTM programs are considered "activities that improve health care quality."

Enrollment and Targeting

Sponsors must enroll targeted beneficiaries in their MTM program using an opt-out method of enrollment only as required in 42 CFR § 423.153(d)(1)(v). Therefore, each year sponsors must auto-enroll targeted beneficiaries who meet the eligibility criteria unless the beneficiary declines enrollment. Sponsors must identify targeted beneficiaries for enrollment in their MTM programs at least quarterly during each year (42 CFR § 423.153(d)(1)(vi)).

Enrolled beneficiaries may refuse or decline individual services without having to disenroll from the MTM program. In very rare occurrences, a beneficiary may request to be permanently opted out of the MTM program in both the current and future years. Should an enrollee desire to permanently opt out of the plan's MTM program, the plan should honor the request and not re-target the beneficiary in future contract years. However, if the beneficiary actively seeks enrollment into the MTM program later, perhaps due to a level of care change, the plan must allow the beneficiary to participate as long as the beneficiary meets the eligibility criteria. In all cases, CMS expects sponsors to maintain documentation of beneficiary requests to opt out of the MTM program.

Once beneficiaries are enrolled, sponsors should not disenroll a beneficiary from the MTM program if they no longer meet the eligibility criteria at 42 CFR § 423.153(d)(2). Beneficiaries should remain enrolled in the program for the remainder of the calendar year. Targeting and enrollment into the MTM program, if eligible, would occur again the following calendar 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 their MTM program at the contract ID level in the next program year. This targeting could be done to auto-enroll eligible beneficiaries in the MTM program early in the next program year to prevent interruption of MTM interventions. To project if a beneficiary will meet the targeting criteria for the new program year, sponsors may use claims from previous or current years.

Required MTM Services

Plan sponsors must offer a minimum level of MTM services to each beneficiary enrolled in the program that includes <u>all</u> of the following, as specified in 42 CFR § 423.153(d)(1)(vii):

1. Interventions for both beneficiaries and prescribers.

2. An annual comprehensive medication review (CMR) with written summaries in CMS' Standardized Format under 42 CFR § 423.153(d)(1)(vii)(B) and (D).

    - The beneficiary's CMR must include an interactive consultation, performed by a pharmacist or other qualified provider, that is either in person or performed via synchronous telehealth; 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 due to cognitive impairment, 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, as required at 42 CFR § 423.153(d)(1)(vii)(C).

4. Information about safe disposal of prescription drugs that are controlled substances, drug take back programs, in-home disposal and cost-effective means to safely dispose of such drugs per 42 CFR § 423.153(d)(1)(vii)(E). This information must meet the criteria established in 42 CFR § 422.111(j).

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, perform TMRs at least quarterly to assess medication use on an on-going basis, and provide the required safe disposal information. Also, sponsors are expected to put in place safeguards against discrimination based on the nature of their MTM interventions.

Once a beneficiary has enrolled in the MTM program, sponsors should begin offering or performing the required MTM services. Therefore, 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. Sponsors are expected to use more than one approach when possible to reach all eligible targeted beneficiaries to offer MTM services and not rely only on passive outreach 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). CMS expects plans to develop effective engagement strategies based on their beneficiary population and business model. Sponsors are encouraged to increase beneficiary awareness about their MTM program, promote the value of MTM services to beneficiaries, and ensure that their customer service representatives and staff are familiar with their MTM program.

CMS typically gives plans the latitude to develop MTM programs that meet their beneficiaries' needs within the framework of the applicable statutory and regulatory requirements. Most Part D plans have gained experience with their ARB population through DMPs and other Part D opioid-related policy, and we expect plans to draw on this experience when working with their clinical teams, including any downstream entities, in developing clinically appropriate MTM interventions for these individuals.

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 successfully 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 successfully offer the CMR within one year of the last CMR offer. A CMR offer cannot be deemed successful if a mailed letter is returned or the beneficiary phone number on file is invalid. Sponsors should maintain documentation of offers (including the date of the offer and who the offer was delivered or communicated to).

Each CMR must include an interactive consultation to review the beneficiary's medications (including prescriptions, over-the-counter (OTC) medications, herbal therapies, and dietary supplements) performed in real-time, that is either in person or via synchronous telehealth, by a pharmacist or other qualified provider and a summary of the results of the review must be provided to the MTM enrollee in CMS' Standardized Format. Plans have the discretion to determine whether the CMR can be performed in person or using the telephone, video conferencing, or another real-time method.

Sponsors should maintain documentation regarding the delivery of CMRs including who performed the CMR, who received the CMR, and when the CMR was delivered, as well as a copy of the summary and its delivery date.

We expect the CMR to meet the following professional service definition:[4]

> *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 in person or synchronous telehealth 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 condition(s).*

Cognitively Impaired Beneficiaries (in any care setting)

Under 42 CFR § 423.153(d)(1)(vii)(B)(2), if the beneficiary is unable to accept the offer to participate in the CMR due to cognitive impairment, the MTM provider may perform the CMR with the beneficiary's prescriber, caregiver, or other authorized individual.

If the MTM provider determines that a beneficiary is unable to accept the offer to participate in a CMR but is unable to identify the beneficiary's prescriber, caregiver, or other authorized individual, such as a health care proxy or legal guardian, to participate in the CMR, a CMR

[4] Adapted from the National MTM Advisory Board definition with a revision to reflect that CMS permits a CMR to be conducted via telehealth. Gamble KH. MTM Advisory Board updates definition of key pharmacist service. *Pharmacy Times*, August 07, 2011. Available at https://www.pharmacytimes.com/view/mtm-advisory-board-updates-definition-of-key-pharmacist-service. Accessed February 27, 2024.

cannot be performed. However, sponsors are required to perform the other required MTM services. If asked, plan sponsors should be able to present documentation or a rationale for these determinations. Note that although ICD-10 codes may be used to gather information about a beneficiary's medical conditions, Part D sponsors should not rely on such administrative information alone to determine whether a beneficiary is cognitively impaired and unable to accept the offer to participate in their own CMR.

The flexibility to perform the CMR with an individual other than the beneficiary, as described above, requires that the beneficiary be unable to accept an offer to participate due to cognitive impairment, and does not apply to situations where the Part D sponsor is unable to reach the beneficiary (such as no response by mail, no response after one or more phone attempts, or lack of phone number or address) and there is no evidence of cognitive impairment, or where the beneficiary declines the CMR offer. CMS acknowledges that beneficiaries may invite other individuals, such as their caregiver or authorized representative, to join them in the CMR. This situation is outside of the policy established under 42 CFR § 423.153(d)(1)(vii)(B)(2) for when the beneficiary is unable to accept the offer to participate due to cognitive impairment. CMS requires Part D sponsors to comply with all Federal and State laws regarding confidentiality and disclosure of medical records or other health and enrollment information per 42 CFR § 423.136. Accordingly, we expect Part D sponsors and MTM providers to comply with the Health Insurance and Accountability Act (HIPAA) and maintain documentation of who participated in the CMR.

Further, perceived barriers due to a beneficiary's social determinants of health (SDOH) do not mean that the beneficiary is unable to participate in a CMR. MTM providers are expected to engage the targeted population in a manner that these beneficiaries can understand and use, regardless of any language or other barriers that exist. CMS also cautions that the failure to provide services to beneficiaries disadvantaged by poverty, language, or other SDOH factors suggests discriminatory practices, which may be in violation of the Social Security Act or other federal requirements regarding access to services.

Relevant federal regulations for MTM programs may include Federal Communications Commission requirements for accessibility, as defined in 47 CFR Part 64 Subpart F; Americans with Disabilities Act (ADA): Nondiscrimination on the Basis of Disability by Public Accommodations and in Commercial Facilities, 28 CFR Part 36; Nondiscrimination on the Basis of Race, Color, National Origin, Sex, Age, or Disability in Health Programs or Activities Receiving Federal Financial Assistance and Programs or Activities Administered by the Department of Health and Human Services Under Title I of the Patient Protection and Affordable Care Act or by Entities Established Under Such Title, 45 CFR Part. 92; Section 504 of the Rehabilitation Act, Nondiscrimination on the Basis of Handicap in Programs or Activities Receiving Federal Financial Assistance, 45 CFR Part 84; and 21st Century Communications and Video Accessibility Act (CVAA). Part D sponsors should also refer to the standards for communications and marketing found at 42 CFR § 423.2267(a).

Optimizing the Delivery of MTM in Long Term Care (LTC) Settings

Sponsors must offer a CMR to all beneficiaries enrolled in their MTM program at least annually,

including enrollees who are in LTC settings.[5] 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 requirements under 42 CFR § 423.153(d).

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 the LTC setting, 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 those of the care team.

Sponsors should ensure that their policies and procedures for offering and delivering CMRs are effective in reaching beneficiaries and take into consideration how to reach the beneficiaries according to their setting and needs. 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 by involving a pharmacist who has a relationship with the LTC facility. To avoid conflicting recommendations resulting from the CMR, the MTM provider should coordinate the recommendations for medication therapy changes as a result of an MTM encounter with the beneficiary's treating physician, the healthcare team at the facility, the beneficiary's caregiver or authorized representative, when applicable, and the consultant pharmacist. Additional consideration could be given to coordinate MTM recommendations with the LTC facility care plan[6] meetings to assess current treatment regimens.

One tool that could be used in nursing homes to identify if a beneficiary is cognitively impaired and unable to accept the offer to participate in the CMR is the Brief Interview of Mental Status (BIMS) in the Minimum Data Set 3.0. The nursing staff, including but not limited to the Director of Nursing, also 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). In the event the beneficiary is unable to accept the offer to participate because they are cognitively impaired, in accordance with 42 CFR § 423.153(d)(1)(vii)(B)(2), the MTM provider may perform the CMR with the beneficiary's prescriber, caregiver, or other authorized individual. 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. If the beneficiary is not cognitively impaired, to better serve the needs of this population, it may be appropriate to conduct the CMR with both the LTC resident and their caregiver or authorized representative.

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[5] A long-term care facility per 42 CFR § 423.100 means a skilled nursing facility as defined in section 1819(a) of the Social Security Act (the "Act"), or a medical institution or nursing facility for which payment is made for an institutionalized individual under section 1902(q)(1)(B) of the Act.

[6] Comprehensive care plans are defined at 42 CFR § 483.21(b).

We recommend that when a targeted beneficiary moves to a LTC facility, Part D plan sponsors 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, Minimum Data Set (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 able to accept the offer to participate in their 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.

Instructions for Implementing the Standardized Format

An individualized, written summary in CMS' Standardized Format must be provided following each CMR and should be provided within 14 calendar days. 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 is unable to accept the offer to participate due to cognitive impairment.

The current Standardized Format and updated technical instructions are posted on the CMS Part D MTM webpage. The Standardized Format for the CMR summary must be approved by the Office of Management and Budget (OMB) through the Paperwork Reduction Act (PRA) process. We requested a 3-year extension of the currently approved Standardized Format (CMS-10396; OMB control number: 0938-1154) with no changes through the PRA process. Once approved, the Standardized Format and instructional documents will be updated on the CMS MTM webpage to reflect this extension.

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 beginning immediately upon enrollment in the MTM program and may address specific or potential medication-related problems. 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 to 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 done with the beneficiary or be system generated. Follow-up interventions with beneficiaries should be interactive with the beneficiary, 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 beneficiaries' prescribers to resolve medication-related problems or provide 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 interactive, 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.

Information about Safe Disposal of Controlled Substances

Pursuant to 42 CFR § 423.153(d)(1)(vii)(E), since January 1, 2022, Part D sponsors have been required to provide to all MTM enrollees, at least annually, as part of the CMR, a TMR, or other MTM correspondence or service, information about safe disposal of prescription drugs that are controlled substances, drug take back programs, in-home disposal, and cost-effective means to safely dispose of such drugs. Under 42 CFR § 423.153(d)(1)(vii)(F), these enrollees must be provided all information required at 42 CFR § 422.111(j), which includes the location of two or more drug take back sites that are available in the community where the enrollee resides. Specifically, the identified drug take back sites must be among the drug take back sites that are generally utilized by people residing in the same community as the MTM enrollee. That is, drug take back sites that are physically located within the shortest travel times. While the requirement under the regulation that Part D sponsors identify two drug take back sites ensures that multiple choices are available to the enrollee, we encourage plans to identify additional community take back sites.

The DEA includes on its website a text file, updated daily, containing the year-round drug disposal locations registered with the DEA. The file is available at https://apps.deadiversion.usdoj.gov/pubdisp/. Links to the file are also posted on the National Prescription Drug Take Back Day website and the DEA's Registration page. Part D sponsors may use the DEA search engine and/or other resources to identify the two or more locations for the MTM enrollee. The information should be accurate at the time the notice is developed and plans have the flexibility to tailor their language to aid in the beneficiary's understanding.

Sponsors may provide the safe disposal information in the CMR, TMR, MTM program Welcome Letter, or other MTM correspondence or service. Although website postings alone will not fulfill the requirement that the information be provided to individual MTM enrollees, Part D sponsors may deliver this information electronically.

Electronic Delivery

Per 42 C.F.R. § 423.2267(d)(2)(ii), Part D sponsors may provide any required material or content electronically with prior consent from the enrollee. This includes the CMR offer letter, TMRs, the CMR Summary in CMS' standardized format, and information about safe disposal of controlled substances. As stated in the Medicare Communications and Marketing Guidelines (MCMG),[7] documents delivered electronically will be considered to be received by the enrollee as of the date the plan sends it; not when the enrollee opens/accesses it.

[7] Medicare Communications and Marketing Guidelines (MCMG) dated February 9, 2022. Available at: https://www.cms.gov/files/document/medicare-communications-and-marketing-guidelines-3-16-2022.pdf.

Multi-Language Insert (MLI)

Per 42 CFR §§ 423.2267(e)(43) and (e)(44), the CMR written summary which, in accordance with 42 CFR § 423.153(d)(1)(vii)(B) and (D), Part D sponsors must provide to all MTM program enrollees who receive a CMR and the safe disposal information that, in accordance with 42 CFR § 423.153(d)(1)(vii)(E), Part D sponsors must provide to all plan enrollees targeted for MTM are required materials subject to the standards for required materials and content. Accordingly, the requirements in 42 CFR § 423.2267(a) and (d) related to formatting and delivery that apply to all required materials and content are also applicable to the CMR and safe disposal information. Similarly, plan sponsors must provide translated materials for the CMR and safe disposal information when the 5 percent language threshold under 42 CFR § 423.2267(a)(2) has been reached.

Website

Pursuant to 42 CFR § 423.2265(b)(13), Part D sponsors are required to include on their websites a separate section or page about the sponsor's MTM program that provides the following:

- An explanation of the MTM program, including eligibility requirements and the purpose and benefits of MTM,
- Information about how to obtain MTM service documents, including the medication list,
- That the service is free,
- A summary of services,
- Information about how the beneficiary will know they are eligible and enrolled into the MTM program, and
- Information about the CMR and TMRs, including how the reviews are conducted and delivered, time commitments, and materials beneficiaries will receive.

In addition to this required information, Part D sponsors should consider providing MTM enrollees with the following:

- Information on who to contact at the plan for more information, with customer service personnel prepared to answer questions about the MTM program, and
- A statement clarifying that MTM services are not considered a benefit.

If possible, this section or page on the website 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.

Sponsors should ensure that the MTM program web page URL reported with their program submission in HPMS is functioning and reflects accurate and up-to-date information. For example, the MTM program information should reflect the sponsor's eligibility requirements for the contract year for both groups of targeted beneficiaries, including beneficiaries who meet the criteria in 42 CFR § 423.153(d)(2) and ARBs as defined at 42 CFR § 423.100, and should also reflect the current cost threshold amount.

The Update Cycle window from December 1 to December 10 provides plan sponsors with an opportunity to make sure their website URLs are functioning before the start of the contract year. For more information on how to update information in the MTM program submission, refer to the section below titled "Change Request Submission Process."

Coordination of Care

MTM can be used to promote the coordination of care. Beneficiaries should be encouraged to take their standardized medication action plan and personal medication list from their CMR summary 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. 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 CMS Interoperability Rule (85 FR 25510) finalized a framework for sharing the data across the industry, which may be suitable to use when conveying data from the MTM provider to the prescriber. The rule includes encouraging use of Health Level Seven (HL7®) Fast Healthcare Interoperability Resources (FHIR®)-based application programming interfaces (APIs) to make other health information more widely accessible.

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. CMS encourages Part D MTM providers to use FHIR-enabled MTM platforms when providing MTM to Part D enrollees to facilitate integration of the MTM service elements into prescribers' EHRs.

Outcomes Measurement

Sponsors are expected to have a process in place to measure, analyze, and report the outcomes of their MTM programs; determine whether or not goals of therapy have been reached; capture medication therapy recommendations and resolutions made as a result of the MTM recommendations; and 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 medication therapy.

- Examples of medication 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 medication therapy problem resolutions made as a result of MTM recommendations include, but are not limited to:
  - Initiate medication;
  - Change medication (such as product in different therapeutic class, dose, dosage form, quantity, or interval);
  - Discontinue or substitute medication (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, address overutilization, and optimize treatment of chronic conditions) and to use the monthly reports via the Part D Patient Safety Analysis Web Portal to help identify beneficiaries for whom targeted MTM interventions may be beneficial to achieve better outcomes.

III. 2025 Medication Therapy Management (MTM) Program Submissions

The CY 2025 MTM program description must be submitted through 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 document titled "HPMS CY 2025 MTM Program User Manual" is available for download through the CY 2025 MTM Program Submission module under Documentation in HPMS. Sponsors should refer to the User Manual while navigating through the MTM Program submission module and performing plan functions. A submission template is provided in the User Manual. This template serves as a guide to the information that must be entered in the HPMS MTM Program Submission module. The User Manual also 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 will be requested to correct deficiencies or if the program meets all of the minimum requirements for approval. Communications will be sent via email tothe 2025 HPMS MTM Program Main Contact, Medicare Compliance Officer, Chief ExecutiveOfficer (CEO), Chief Operating Officer (COO), and Chief Financial Officer (CFO). 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 MTM web page.

IV. Changes to the CY 2025 Module Compared to the CY 2024 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, and to make sure the module is up-to-date with current regulations. Changes to the CY 2025 module include:

- Adding HIV/AIDS to the list of core chronic diseases and requiring plan sponsors to include all ten core chronic diseases specified by CMS in their targeting criteria to identify beneficiaries who have multiple chronic diseases, while retaining sponsors' ability to include additional chronic diseases.
- Requiring sponsors to include all Part D maintenance drugs in their targeting criteria to identify beneficiaries taking multiple Part D drugs, relying on information in a widely accepted, commercially, or publicly available drug database to make such determinations, while retaining sponsors' ability to include all Part D drugs. The option to target only specific Part D drug classes has been removed.
- Updating the MTM cost threshold used to identify beneficiaries who are likely to incur annual costs for covered Part D drugs greater than or equal to the threshold for CY 2025 ($1,623).
- Revising language to confirm that the CMR must include an interactive consultation that is conducted in real-time, regardless of whether it is done in person or via synchronous telehealth.

V. 2025 Medication Therapy Management (MTM) Program Attestations

As a reminder, in addition to the MTM program description an attestation of the Part D sponsor's compliance with Part D MTM program requirements must be submitted through HPMS and must be completed by the CEO, COO, or the CFO. An HPMS confirmation email will be generated and sent after the attestation is received. An approved MTM program submission is required to satisfy the Part D MTM program requirement.

The User Manual located in the CY 2025 MTM Program Submission module contains documentation, screen prints, and standard attestation language to assist Part D sponsors. The process is as follows:

Attestation Submission Process during the Initial Submission Window

- During the initial submission window (May 22 – June 5, 2024), Part D sponsors will submit their CY 2025 MTM program.
- On June 6, 2024, an attestation link will be available for each contract that has submitted a CY 2025 MTM program.
- Attestations for the initial CY 2025 MTM submission will be due two weeks after the initial submission window closes. In CY 2025, attestations must be submitted and received via HPMS by Thursday, June 20, 2024.

Attestation Submission Process due to Contract Exceptions, Change Requests, and Resubmissions

- MTM resubmissions due to contract exceptions, change requests, and resubmission requests require a re-attestation.
- After an MTM resubmission is received, the attestation link will be available immediately.
- Sponsors must re-attest after submitting their updated MTM program.
- The attestation in a resubmission scenario has the same due date as the resubmission itself. For example, if a resubmission is due on June 17, the attestation is also due on June 17.

VI. 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.

Summary

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,
    - Including additional chronic diseases in targeting criteria (i.e., beyond the ten core chronic diseases),
    - Decreasing the minimum number of multiple covered Part D drugs,
    - Including all covered Part D drugs in targeting criteria.

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. CMS expects Part D sponsors will 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.

Change Request Submission Process

The HPMS MTM Program Submission module also allows sponsors to submit MTM program change requests during five Update Windows. Please refer to the 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),
- December 1 – December 10, prior to the contract year (i.e., before effective date of the approved MTM program). Reminder: This is the last window to make sure your website URL is updated before start of contract year.
- 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 should submit their re-attestation via the HPMS attestation link as described above.

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. If your contract needs to make changes to your MTM program outside of these windows or for other questions related to Part D MTM programs, please email **partd_mtm@cms.hhs.gov**. It is essential to include the contract ID(s) in the email request and the applicable contract year if you are requesting to have the submission gate opened in HPMS. If you have any questions on accessing the HPMS MTM Program Submission module, please contact the HPMS Help Desk at 1-800-220-2028.

We appreciate your continued cooperation in administering the Medicare prescription drug benefit.