DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTER FOR MEDICARE

DATE: April 30, 2021

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

FROM: Amy Larrick Chavez-Valdez, Director
Medicare Drug Benefit and C & D Data Group

SUBJECT: Contract Year 2022 Part D Medication Therapy Management Program Guidance
and Submission Instructions

This memorandum provides guidance to Part D sponsors regarding contract year (CY) 2022 Part
D Medication Therapy Management (MTM) programs including:

- Important dates for release of the CY 2022 MTM Program submission module and when
submissions and attestations are due;
- Summary of the requirements for establishing MTM programs for CY 2022;
- Information to assist sponsors with their submissions and attestations;
- Changes to the CY 2022 module compared to last year's module; and
- Instructions for submitting change requests for approved programs.

**I. Important Dates and Information for 2022 MTM Program Submissions and
Attestations**

The CY 2022 MTM program submission deadline is **June 7, 2021** for all Part D sponsors.[1]
These deadlines have been revised from the dates in the January 19, 2021 memorandum titled,
"Contract Year (CY) 2022 Final Part D Bidding Instructions."

Action	Key Date
Release of the CY 2022 MTM Program submission module in the Health Plan Management System (HPMS)	May 24, 2021
2022 MTM Program Submission Deadline	June 7, 2021, 11:59pm PDT
2022 MTM Program Attestation Deadline	June 21, 2021, 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).

The contents of this document do not have the force and effect of law and are not meant to bind the public
in any way, unless specifically incorporated into a contract. This document is intended only to provide
clarity to the public regarding existing requirements under the law.

The revised dates were also included in the "CY 2022 Medicare Parts C and D Annual Calendar" released via HPMS on April 2, 2021.

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 2022 Part D requirements and expectations are summarized in this memorandum; for more detailed information about requirements, see 42 CFR § 423.153(d) and applicable final regulations published in the Federal Register (described later in this memorandum). For detailed guidance, see Chapter 7 of the Medicare Prescription Drug Benefit Manual. Updates to the Manual in accordance with the regulatory changes discussed in this memorandum will be announced through HPMS.

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 submission and approval process. These requirements do apply to Employer Group Waiver Plans (EGWPs).

II.   Summary of 2022 Medication Therapy Management (MTM) Program Requirements

Per § 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 § 423.153(d)(1)(vii).

Recent Changes

CMS issued a final rule (86 FR 5864)[2] on January 19, 2021 that implements changes to the MTM program beginning January 1, 2022. The final rule expands the definition of beneficiaries targeted for MTM to include at-risk beneficiaries (ARBs) under a Drug Management Program (DMP), regardless of whether those individuals meet other MTM targeting criteria. It also requires plans to provide all MTM enrollees with information about the safe disposal of prescription drugs that are controlled substances, including opioids, and requires that plans include on their websites a separate section or page about MTM programs. In addition to these regulatory changes, the 2022 MTM program annual cost threshold increased to $4,696. The 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 § 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.

   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 conditions 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/Disabling Mental Health Conditions).

---

[2] "Medicare and Medicaid Programs; Contract Year 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Program, and Programs of All-inclusive Care for the Elderly" (CMS 4190-F2)

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.

In defining multiple Part D drugs, sponsors cannot require more than eight 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 two and eight.

AND

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

The 2021 MTM program annual cost threshold is $4,396. The MTM program annual cost threshold is updated for 2022 using the annual percentage increase of 7.31%, as specified in the [Announcement](#) of Calendar Year (CY) 2022 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies dated January 15, 2021. Therefore, the 2022 MTM program annual cost threshold is $4,696.

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.

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

All existing ARBs – that is, beneficiaries with an active coverage limitation under a DMP as of January 1, 2022, although such limitation may have commenced prior to January 1, 2022 – as well as ARBs identified on or after January 1, 2022, must be targeted for enrollment in MTM.

There may be some overlap between the populations that meet the eligibility criteria under (1) and (2), e.g., a beneficiary who is an ARB under the plan's DMP (2) who also meets MTM criteria based on having multiple chronic diseases, multiple Part D drugs and meeting the cost threshold (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 an enrollee meets the eligibility criteria under group (1) and/or (2), the enrollee 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 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 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 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.

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 § 423.153(d) and are offered by Part D sponsors (including MA organizations that offer MA-PD plans (described in § 422.2420(a)(2)) are "quality improvement activities" (QIAs).[3]

Enrollment and Targeting

Sponsors must enroll targeted beneficiaries using an opt-out method of enrollment only as required in § 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 the MTM program at least quarterly during each year (§ 423.153(d)(1)(vi)).

Enrolled beneficiaries may refuse or decline individual services without having to disenroll from the MTM program. Please note that 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 enrollee actively seeks enrollment into the MTM program at a later time, perhaps due to a level of care change, the plan must allow the enrollee to participate as long as he or she meets the eligibility criteria. In all cases, CMS expects sponsors to maintain documentation of beneficiary requests to opt out of the MTM program.

Once enrolled, sponsors should not disenroll a beneficiary from the MTM program if they no longer meet the eligibility criteria as defined above. Beneficiaries should remain enrolled in the

---

[3] 42 CFR §§ 422.2430(a)(1)(ii), (4)(i); 423.2430(a)(1)(ii), (4)(i)

program for the remainder of the calendar year. Targeting and enrollment, 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 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.

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 § 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 § 423.153(d)(1)(vii)(B) and (D).

3. Quarterly targeted medication reviews (TMRs) with follow-up interventions when necessary as required at § 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 § 423.153(d)(1)(vii)(E). This information must meet the criteria established in § 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 (i.e., TTY if phone based, braille if mail based, etc.).

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 and to 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 earlier Part D opioid overutilization 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, person-to-person, or telehealth medication review and consultation of the beneficiary's medications performed by a pharmacist or other qualified provider and may result in a recommended medication action plan. A summary of the results of the review must be provided to the MTM enrollee in CMS' Standardized Format. The MTM provider should perform the CMR in real-time and include prescriptions, over-the-counter (OTC) medications, herbal therapies, and dietary supplements in the review.

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 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 Model[4] and the Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes Resource Guide[5] for examples of industry standards of care for delivering MTM and CMRs.

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, the MTM provider may perform the CMR with the beneficiary's prescriber, caregiver, or other authorized individual, such as a health care proxy or legal guardian. CMS considers that a beneficiary may be unable to accept an offer to participate in the CMR only when the beneficiary is cognitively impaired and cannot make decisions regarding their medical needs. The flexibility to perform the CMR with an individual other than the beneficiary, as described above, does not apply to situations where the 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), if there is no evidence of cognitive impairment, or where the beneficiary declines the CMR offer.

If the MTM provider determines a beneficiary is unable to accept the offer to participate in a CMR, but is unable to identify another individual who is able to participate, a CMR cannot be performed. However, sponsors are required to offer 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.

CMS acknowledges that beneficiaries may request that the MTM provider reach out to their caregiver or other authorized individual to participate in the CMR. This situation is outside of the guidance provided for when the beneficiary is unable to accept the offer to participate due to

---

[4] American Pharmacists Association, National Association of Chain Drug Stores Foundation. Medication therapy management in community pharmacy practice: core elements of an MTM service (version 2.0). March 2008. Accessed March 8, 2021 at:
http://www.pharmacist.com/sites/default/files/files/core_elements_of_an_mtm_practice.pdf.
[5] The Patient-Centered Primary Care Collaborative (PCPCC). The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes. 2012. Accessed March 8, 2021 at:
http://www.pcpcc.org/sites/default/files/media/medmanagement.pdf.

cognitive impairment. However, in reviewing such requests, 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. Other relevant federal regulations for MTM programs include:

- Federal Communications Commission requirements for accessibility, as defined in 47 CFR Part 64 Subpart F,
- Americans with Disabilities Act (ADA): SUBCHAPTER II - PUBLIC SERVICES, PART A - Prohibition Against Discrimination and Other Generally Applicable Provisions,
- 21st Century Communications and Video Accessibility Act (CVAA), and
- Standards for Part D sponsor communications and marketing found at 42 CFR § 423.2268(a)(7).

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.[6] 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 § 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 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 are effective for beneficiaries taking into consideration how to reach the beneficiary 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

---

[6] Sponsors should refer to Chapter 5 of the Prescription Drug Benefit Manual for a description of the types of facilities which are considered LTC.

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 medication 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 because they are cognitively impaired, 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).

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, 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.

One tool that could be used in nursing homes to identify if a beneficiary is cognitively impaired and cannot accept the offer 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.[7] 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.

---

[7] Memorandum 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.*

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 l
"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 l
"Ability to Understand Others" Scoring
0 = Understands
1 = Usually understands
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 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 cannot accept the offer to participate. The Standardized Format with detailed instructions for implementation, as well as 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 involves 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.

The Standardized Format must be approved by the Office of Management and Budget (OMB) through the Paperwork Reduction Act (PRA) process. On February 1, 2021, OMB extended approval of the current MTM Standardized Format (Form CMS-10396, OMB Control Number 0938-1154) through February 29, 2024. Based on feedback from consumers and other stakeholders and Section 6103 of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment—(SUPPORT) for Patients and Communities Act (SUPPORT Act), we proposed revisions to the Standardized Format with the intent of optimizing the utility of the CMR summary for beneficiaries while reducing burden on Part D sponsors (See 85 FR 10444). CMS will announce on the Federal Register and through HPMS when the revised format is available for the 30-day comment period.

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 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.

Information about Safe Disposal of Controlled Substances

Pursuant to 42 CFR § 423.153(d)(1)(vii)(E), beginning January 1, 2022, Part D sponsors must 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), such 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.

Sponsors may provide this information in the CMR, TMR, MTM enrollment welcome letter, or other MTM correspondence or service. Information may be disseminated across one or more types of communications as long all required information is furnished annually. Additionally, if an MTM enrollee declines the CMR or other MTM services, the sponsor is still responsible for providing the required safe disposal information, which could be done through another 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 (e.g., through a member portal), provided the plan can document the individual received the information.

Website

Pursuant to 42 CFR § 423.2265(b)(13), Part D sponsors are required by January 1, 2022 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 these requirements, Part D sponsors should consider providing enrollees with information including:

- 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 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. Sponsors should ensure that the MTM program web page URL reported with their program submission in HPMS is accurate and functioning.

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 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 National Council for Prescription Drug Programs (NCPDP) WG10 MTM and Pharmacist Clinical Services Task Group prepared a Health Level Seven (HL7®) Clinical Document Architecture (CDA) template[8] using standard code sets and nomenclature to support the rendering of the CMR summary in Standardized Format from digital data stored in electronic health records. The recent 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 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; whether or not goals of therapy have been reached; capture medication 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 medication therapy.

- Examples of medication therapy problem recommendations made as a result of MTM services include, but are not limited to:
    - Needs additional therapy;

---

[8] HL7 CDA® R2 Implementation Guide: Medication Therapy Management (MTM) Templates, Release 1 - US Realm available at: https://www.hl7.org/implement/standards/product_brief.cfm?product_id=414. Accessed March 31, 2021.

- o Unnecessary drug therapy;
- o Dosage too high;
- o Dosage too low;
- o More effective drug available;
- o Adverse drug reaction;
- o Medication Non-compliance/Non-adherence.

- Examples of medication therapy problem resolutions made as a result of MTM recommendations include, but are not limited to:
  - o Initiate medication;
  - o Change medication (such as product in different therapeutic class, dose, dosage form, quantity, or interval);
  - o Discontinue or substitute medication (such as discontinue drug, generic substitution, therapeutic substitution, or formulary substitution);
  - o 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. 2022 Medication Therapy Management (MTM) Program Submissions

The CY 2022 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 User Guide titled, "HPMS CY 2022 MTM Program User Manual", is available for download through the CY 2022 MTM Program Submission module under Documentation. Sponsors should refer to the User Guide while navigating through the MTM Program submission module and performing plan functions. A submission template is provided in the HPMS User Guide. This template serves as a guide to the information that must be entered in the HPMS MTM Program Submission module. The User Guide 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 to the 2022 HPMS MTM Program Main Contact, Medicare Compliance Officer, Chief Executive Officer (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 CMS MTM web page.

IV.   Changes to the CY 2022 Module Compared to the CY 2021 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 2022 module include:

- The addition of at-risk beneficiaries (ARBs) as targeting criteria under § 423.153(d)(2).
- A section regarding the distribution of 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.
- Additional options added for data evaluated for targeting.
- Update of the 2022 MTM program annual cost threshold to $4,696, as finalized in the Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies.

V.   2022 Medication Therapy Management (MTM) Program Attestations

As a reminder, an attestation of the Part D sponsor's compliance with Part D MTM program requirements should be submitted in addition to the MTM program description 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 Guide located in the CY 2022 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 <u>initial</u> submission window (May 24 – June 7, 2021), Part D sponsors will submit their CY 2022 MTM program.

- After June 7, 2021, an attestation link will be available for each contract that has submitted a CY 2022 MTM program.

- Attestations for the initial CY 2022 MTM submission will be due two weeks after the initial submission window closes. In CY 2022, attestations must be submitted and received via HPMS by Monday, June 21, 2021.

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

- MTM <u>resubmissions</u> 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 should 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,
   - 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. 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 Guide 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).
- 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. 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 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.