



## **Part D Enhanced Medication Therapy Management (MTM) Model:**

### **Responses to Stakeholder Inquiries**

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This document provides guidance and clarification to stakeholders regarding implementation of the Part D Enhanced Medication Therapy Management (MTM) model test. The Enhanced MTM model will test changes to the Part D program that would achieve better alignment of PDP sponsor and government financial interests, while also creating incentives for robust investment and innovation in better MTM targeting and interventions. More information about the model test is available in the Enhanced MTM model's Request for Applications (RFA) and other documents available at [innovation.cms.gov/initiatives/enhancedmtm](http://innovation.cms.gov/initiatives/enhancedmtm).

### **Enhanced MTM Learning and Diffusion**

#### **1. Can MTM programs who are not participating in the Enhanced MTM model attend learning events?**

Understanding that the Part D market environment is very competitive and there is a need to protect proprietary interests, CMS will determine if the event is appropriate for non-participants on an event-by-event basis. CMS plans to hold multiple learning events over the model performance period to ensure that participants have a shared understanding of certain topics.

**2. Will CMMI roll out MTM strategies that are proven effective to the entire Part D MTM program prior to the end of the five-year testing period?**

The model will be evaluated on a rapid-cycle basis throughout the test period. To the extent that policy-relevant conclusions can be drawn prior to the end of the testing period, they may inform broader CMS policy-making.

## **Enhanced MTM Program Design**

**1. How will the Enhanced MTM model engage patients during the prescription process if the model does not allow direct reimbursement to prescribers?**

The Enhanced MTM model provides incentives for Part D plans to find innovative ways to work with prescribers to reduce medication-related risks and lower Medicare expenditures. In so doing, the model aims to align the incentives for PDP sponsors with those of prescribers who we believe are already motivated to find ways to improve the health care and outcomes of their patients who use medication. We also note that the Enhanced MTM model in no way restricts providers' existing ability to claim Medicare fee-for-service reimbursement for evaluation and management or related services.

In developing this model, we heard from physicians (For more detail, please see the related Technical Expert Panel: <https://innovation.cms.gov/Files/x/mtm-prescriber-panel.pdf> ) that prescribers often lack reliable information on which drugs their patients are actually taking and lack sufficient resources to thoroughly review beneficiaries' medications. These barriers can complicate a prescriber's ability to provide the specialized care a beneficiary needs. Plans participating in the Enhanced MTM model may address this barrier by providing updated and reconciled medication data or allowing a prescriber to order a pharmacy consult to review a patient's medication regimen.

**2. Can beneficiaries opt out of participation in the model? Do beneficiaries have to opt in to receive Enhanced MTM services?**

Beneficiary participation in Enhanced MTM model activities is voluntary, and targeted beneficiaries may opt out of offered services at any time. Beneficiaries are not required to opt-in to the model test prior to a plan reaching out to offer enhanced MTM services.

**3. Can plans propose strategies for the provision of cost sharing assistance to Enhanced MTM enrollees?**

Yes. The Enhanced MTM model gives plans the opportunity to target and remove barriers to proper medication use at an individual level. As such, CMS expects that plans will target beneficiaries using risk-stratified criteria, engage with beneficiaries to determine their barriers to effective optimal medication use, and provide interventions that directly address those identified barriers.

If a plan determines that a beneficiary's barrier to optimal use of a specific drug therapy is financial need, the plan may be authorized under the MTM uniform cost sharing waiver to provide reduced cost sharing. CMS will require detailed information on the methods for determining eligibility for such cost sharing reductions as part of the application process. CMS does not anticipate permitting cost-sharing reductions as an intervention in this model without individual beneficiary-level need assessment and confirmation.

**4. Can plans propose a strategy where the beneficiary is at financial risk if they aren't adherent to their medications, e.g., a copay increase?**

No, plans are not permitted to restrict benefits or increase cost-sharing in this model. The purpose of this model is to encourage participating plans to design MTM programs that target, engage, and provide tailored services to enrollees at risk for medication-related issues in an individualized manner. This model is designed to test innovations in medication therapy management interventions, not modifications in plan benefits. CMS is hopeful that this model will encourage participating plans to consider methods to encourage positive enrollee behavior beyond benefit design.

**5. Would plans be allowed to encourage lower cost sites of care for medication-related services (e.g., bill for specialty infusion services under this model)?**

To the extent that participants want to incorporate certain types of pharmacies or providers into their Enhanced MTM program to reduce medication-related risks, CMS looks forward to reviewing these proposals. That said, the provision of Enhanced MTM items or services may not be tied to use of specific network pharmacies for dispensing of Part D drugs. The model does not waive Part D network access requirements or any other Part D requirement not specifically listed in the Enhanced MTM Request for Applications. CMS believes that a successful participant in this model will design an MTM program that effectively engages enrollees at risk for medication-related issues "where they are" as opposed to requiring the enrollee to come to the plan or plan preferred providers for assistance in overcoming a barrier to improved medication use.

**6. Would participating plans be allowed to alter their formulary or relax utilization management criteria for enrollees?**

No. Formulary requirements for Part D plans are not waived as part of this model. However, applicants are encouraged to propose innovative approaches to ensuring targeted beneficiaries are receiving optimal prescription drug therapy.

**7. Are nursing home residents considered an at-risk population?**

CMS expects applicants to develop Enhanced MTM programs that systematically target populations at risk for medication-related issues. All current MTM requirements are waived in this model, and therefore it is up to the plan to propose which populations to target. In order to reduce Medicare Part A and B expenditures by 2% across all plan participants and qualify for the performance-based payment, plans will need to judiciously target populations likely to yield significant savings through participation in the plan-developed Enhanced MTM program. Dual eligible beneficiaries in SNF/NF settings have some of the highest avoidable re-hospitalization rates of all Medicare beneficiaries in part due to misaligned incentives between Medicaid and Medicare coverage rules. If a plan determines that nursing home residents are an appropriate a population to target, they may include them in their application to CMS for model participation.

CMS believes that there may be distinct benefits of administering the CMR in the vulnerable LTC population (especially in aligning patient/caregiver goals). MTM can be used as an opportunity to align medication use with the beneficiary's goals and wishes in addition to the care team's. PDP MTM programs can be impactful in the LTC setting when used to identify overuse, medications without a clear indication, suboptimal dosing, and polypharmacy, especially to the resident/caregiver.

## **Quality and Performance Monitoring**

**1. How will Quality & Performance be monitored?**

CMS views this model as a test of innovation for MTM programs, and therefore does not aim to penalize plans for trying new, inventive strategies. Therefore, CMS is not prescribing specific quality measures by which plans will be incentivized. That said, CMS hopes that this model will yield valuable information to inform the development of potential future outcomes-focused quality measures.

CMS will collect MTM encounter data incorporating elements such as beneficiary identifiers, dates and locations of service, provider identifiers, and coupled SNOMED codes to detail MTM-related activities and outcomes. This data will be used in part to assess sponsors' performance with respect to

their approved model intervention plans. Any sponsor that submits data that is substantially inconsistent with the strategies, costs, and utilization assumptions approved in its model application will be subject to follow-up by CMS, and possibly to requests for corrective action and other compliance actions. The MTM encounter data will also be used to construct and pilot certain performance indicators, which will be evaluated over time to see how well they are correlated with actual improved outcomes. CMS will seek public comment on this data reporting in the near future with the intent to issue specifications by mid-2016.

In addition to the uniform set of data, CMS expects each stand-alone basic PDP sponsor to identify and propose its own metrics for its internal progress assessment and learning system. The stand-alone basic PDP sponsor metrics and associated data elements will vary based on the PDP sponsor and the MTM interventions proposed by the sponsor. CMS will use both the uniform and plan-sponsor-specific indicators as a means to monitor compliance with the proposed enhanced MTM program, characterize the interventions implemented by the PDP sponsors, and evaluate the impacts of the model.

## **2. How will plan participation impact MTM-related Star Ratings reporting?**

CMS is hopeful that the flexibilities offered in the Enhanced MTM model will improve the quality of care available to beneficiaries enrolled in Medicare Part D. These improvements may manifest as improvements in the individual measures underlying the Medicare Part D star ratings. We recognize the concern that sponsors not eligible to participate in the Enhanced MTM model will not have access to the same flexibilities and do not wish to be placed at a disadvantage relative to participating sponsors. We also recognize that participants in the Enhanced MTM model do not want their improvements in individual measures discounted. We are considering several alternatives for potential Enhanced MTM model-related adjustments to the star ratings with the aim of accommodating each of these concerns, and welcome comments or suggestions for methods for doing so.

## **3. Can a plan with a less than 3-star rating be selected for this model test?**

Any applicant with a contract that has 2016 Medicare Star Ratings with a Part D summary score less than 3.0 will be subject to additional requirements in order successfully apply to the model. The applicant must provide a detailed explanation to CMS regarding how participation in the model will lead to improvements in plan quality and Star Ratings measurements. CMS will determine if an applicant with a Star Rating less than 3.0 may participate in the model on a case-by-case basis.

## Prospective Payments

- 1. Are the pharmacy item and service costs associated with the MTM intervention included in the funds that must come from the new prospective payments or could these costs come from the sponsor's Part D operating margin?**

As part of this model, CMS will offer participating plans a new per-member-per-month (PMPM) prospective payment. This payment may fund enhanced items and services, improved system linkages, and other model activities, as approved by CMS. Model costs incurred for the pharmacy's items and services and funded out of this payment must be separately contracted and accounted for in a manner that can be audited by CMS. All estimated costs for MTM targeting, engagement, and intervention strategies and services must be approved by CMS in the application process and be accounted for in the prospective payment calculation submitted to CMS for review. The only sources of funding that may be used under the model will be the new prospective payments, or negligible administrative funds from the sponsor's Part D operating margin. CMS will also collect retrospective cost reports to better understand MTM cost drivers.

- 2. Can plans embed upfront costs associated with acquiring appropriate software to implement Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) recording, prepare internal IT systems, and train staff into the cost assumptions that plans must prepare for their model test applications?**

CMS understands that participating plans may need to develop or contract for additional health information technology in order to meet the model's data reporting requirements, which include the submission of encounter data that will include but is not limited to SNOMED CT data, or improve system linkages between prescribers, pharmacists, and plans. Plans are allowed to include IT-related costs that directly and primarily support the Enhanced MTM model in their prospective payment calculation. Evaluation of the reasonableness of such estimates will be subject to actuarial review, including comparison with other proposals, and may require additional supporting documentation.

We note that plans will likely aim to minimize these costs by weighing all options for obtaining the necessary IT or data collection capabilities. In order to qualify for the performance-based payment on an annual basis, plans must first reduce Part A and B spending by an amount equivalent to the total prospective payment received that year before savings can count toward the 2% reduction required to receive the payment. Accordingly, a lower annual prospective payment increases the likelihood that a plan will qualify for the model's performance-based payment incentive.

CMS encourages all plans to submit proposals to administer a robust Enhanced MTM program that is capable of qualifying for the performance-based payment under reasonable assumptions. Excessively high IT costs in the prospective payment could jeopardize a plans' ability to meet this requirement.

## Performance-based Payments

**1. What statistical matching methodology will CMS use to identify the comparison population for purposes of computing the benchmark for the performance-based payment?**

CMS intends to identify a comparison group that is similar to the intervention group (i.e. the beneficiaries in participating plans) in terms of population characteristics, geographic characteristics, and participation in CMMI and non-CMMI initiatives. A detailed methodology for constructing this comparison group is currently under development and CMS intends to release more information in future.

**2. Will the 2% savings be adjusted for annual rate increases in Medicare Prospective Payment System adjustments done during the pilot, i.e., will annual rate changes be neutralized when calculating savings?**

Yes – the benchmark methodology will be designed to either directly (or indirectly through construction of appropriate comparison groups) control for changes in Medicare fee-for-service payment unrelated to the model (including payment system rate updates).

**3. How will CMS determine how other interventions (e.g., beneficiary participation in alternative payment models) in addition to the enhanced Part D MTM program, impact beneficiary Parts A and B claims cost during the model?**

We will survey a range of data sources to identify any beneficiary overlap in other health care transformation activities such as ACO or Bundled Payment initiatives. To the greatest extent possible, we intend to control for beneficiary alignment in order to minimize confounding.

## Medicare Data Sharing with PDP Sponsors

**1. Will CMS notify Part D sponsors when patients undergo a transition in care?**

No, CMS will not directly notify Part D sponsors each time a beneficiary undergoes a transition of care. Through this model, CMS is providing plans with flexibility to design innovative MTM programs that include targeting, engagement, and intervention strategies to decrease medication-related risks in enrolled beneficiaries. Plan-developed strategies could include designing cooperative agreements with local providers to receive notification when plan enrollees undergo a transition of care.

CMS will provide participating plans with requested Part A and B data through this model, however this data will only be provided periodically and is unlikely to be appropriate for real-time monitoring of patient care status. Plans that want access to more current information should incorporate alternative strategies into their Enhanced MTM program.

**2. How frequently will CMS share Part A & B data with plans during the five-year test period?**

As part of this model CMS will provide participating plans with requested Medicare Parts A and B data to support identification of fee-for-service medical services enrolled beneficiaries have received and to provide greater context for each beneficiary's medication regimen. CMS has requested that plans outline the frequency and type of data needed in their application. In general, CMS will make every effort to meet plan data requests, to the extent technically feasible.

## **Plan Marketing and Member Communications**

**1. Can participating plans disclose information about model participation to beneficiaries during plan enrollment? What can participating plans communicate to eligible beneficiaries regarding participation in the Enhanced MTM model and associated benefits?**

Plans participating in the Enhanced MTM model are not allowed to market and disclose participation in the model to potential enrollees. CMS is testing the impact of increased flexibility and aligned financial incentives on MTM program effectiveness. We are not testing the impact of Enhanced MTM programs on plan enrollment.

However, once a beneficiary has been enrolled and has been identified as in need of MTM interventions, then plan representatives may provide that individual specific information about applicable items and services available due to the plan's participation in the model. However, since by design model interventions are highly individualized, we do not believe such notices will typically be standardized. (However, to the extent that standardized communications are used, CMS reserves the right to review and approve beneficiary communications.) Rather, in conducting beneficiary outreach, CMS expects sponsors to rely more heavily on more personalized strategies, such as contacts from trusted community pharmacists or their medical providers, because for certain populations these may be more effective than call-center or mail contacts from the PDP. All communications should be intentionally designed to facilitate beneficiary involvement in health care decisions and to improve health literacy.

CMS expects plans to develop effective engagement strategies, including innovative and tailored communications to offer these enrollees assistance in meeting their personal goals of therapy. We expect

that the need for specific MTM items and services will often only be known following person-to-person engagement that identifies a specific barrier to effective medication use.

## **PDP Application Requirements**

### **1. Do plans have to submit a list of the vendors they are working with by the application due date?**

As part of the application, eligible plans will need to provide detailed description of all potential payment flows between sponsor and the types of entities included in MTM program design including those contracted to provide or support MTM interventions. However, we recognize that applicants may not have finalized their contracting strategy for proposed Enhanced MTM programs, and that specific vendors may be identified on a tentative basis. CMS may request additional detail at a later date.

### **2. How should plans submit an application if only one PBP is eligible to participate? Can plans continue to submit all MTM details at the contract level?**

Plan sponsors with contracts that include PBPs that are not eligible to participate in the model must ensure that those non-participating plans comply with all standard Part D requirements, including the submission of MTM program details. The current MTM requirements are waived for the PBPs approved to participate in the Enhanced MTM model and data on participating PBPs will not continue to be reported under the current MTM program. This MTM data must instead be reported in accordance with model terms and conditions, and must be excluded from other Part D reporting.

## **Other**

### **1. Does CMS have a plan in place to encourage plans to contact and solicit pharmacies participation?**

We believe that the structure of this model incentivizes PDP sponsors to extend their use of pharmacies and pharmacists in order to reach all segments of their at-risk population. But the model does not prescribe how PDP sponsors will accomplish that goal. While CMS believes that pharmacists can be a vital and trusted resource for beneficiaries in the medication therapy management process, participating plans must determine what role specific pharmacies will play in their Enhanced MTM program.