



CMS-CMMI Releases Enhanced Medication Therapy Management (MTM) Model Test Beginning in January 2017

Pursuant to a [memorandum issued on September 28, 2015](#), the Centers for Medicare and Medicaid Services (CMS) Center for Medicare and Medicaid Innovations (CMMI) will begin testing new payment models for medication therapy management (MTM) in January 2017 for stand-alone prescription drug plans (PDPs) under the Medicare Part D program. Below is a summary of CMS' requirements to participate. AMCP has advocated for revisions to the CMS MTM criteria and payment models for many years. AMCP is pleased that the enhanced model includes many of the provisions it sought for many years, including flexibility with MTM criteria and changes to the payment system for MTM. A list with links to AMCP's correspondence to CMS on MTM appears at the end of this summary. AMCP will continue to work with CMS and other stakeholders to consider the details to implement the model, particularly the development of quality measures.

The enhanced MTM test model will be in place for five years, from 2017-2021, and then will continue to provide performance-based payments for an additional two years after the model period. The model is designed to provide additional flexibility for PDPs to perform individualized and risk-based interventions. It would accomplish this by providing prospective payments for MTM interventions outside of the Part D bid and performance payments through an increased direct subsidy to plans that both reduce fee-for-service expenditures in Medicare Parts A and B and meet quality and data reporting requirements.

Through this enhanced MTM test model, CMMI intends to examine the impact of waiving MTM requirements for PDPs and providing financial incentives for innovation. The research will also examine the impact on patient outcomes and satisfaction; impact on plan expenditures, including plan bids, and other Medicare spending; market impact of the program; and the proportion of beneficiaries impacted. CMMI seeks to provide PDPs with alternative payment models to achieve the goals of MTM, which are optimized therapeutic outcomes through improved medication use, and reduced risk of adverse events while reducing Medicare expenditures. This approach also encourages greater participation by pharmacies and prescribers in MTM. Pharmacies may be companies contracted by PDPs to provide MTM items and services under this expanded approach. PDPs may not compensate prescribers for MTM referrals and consultation.

The enhanced test model will be available to plans in the following five Part D regions:

- Region 7—Virginia
- Region 11—Florida
- Region 21—Louisiana
- Region 25—Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming
- Region 28—Arizona

Any PDP that meets CMS' requirements outlined in this proposal may elect to submit an application to participate, but the plan enhancement must apply to all plans offered in the selected regions. The requirements include three years of participation in Part D prior to 2017 and a minimum enrollment of 2,000 beneficiaries. Generally, PDPs must have at least a 3-star rating to participate, but those that do not meet that threshold may be considered on a case-by-case basis. Participating PDPs will also be required to meet minimum quality and reporting requirements.

Although PDPs will not be required to target specific populations, CMS expects that priority will be given to the following indicators:

- Chronic diseases and conditions where treatment and outcomes are highly dependent on medications, such as diabetes, CHF, COPD, and asthma;
- Transitions of care;
- Polypharmacy with the use of multiple prescribers;
- Frequent recent utilization of health care services;
- Lack of social support; and,
- First fills of certain medications with difficult side-effect or complication profiles.

Participating PDPs will not submit standard MTM programs for approval to CMS, but rather will provide CMS with descriptions of its enhanced MTM program eligibility and targeting criteria. Page 21 of the memorandum provides a model timeline: CMMI will release a request for applications (RFA) in October 2015 and applications must be submitted by January 2016. By September 2016, CMMI will finalize agreements. CMS encourages PDPs to begin developing and implementing new MTM approaches prior to the release of the RFA.

Enhanced and Individualized MTM Strategies (pages 4-6)

On page 5 of the memorandum, CMS provides an extensive list of strategies to enhance MTM. Plans will also be given the flexibility to use documentation other than the comprehensive medication review for beneficiary and provider communication and engagement.

Financial Incentives in Enhanced Model (pages 7-9)

The approach includes providing plans with regulatory flexibility and payment reform incentives. The financial incentives include both prospective payments to PDPs and performance-based payments for demonstrated success in reducing Medicare Parts A and B expenditures and achieving quality goals.

Direct Prospective Payments to Plans

MTM-related costs would not be included in PDP bids. PDPs will receive a per-member-per-month (PMPM) prospective payment from CMS to provide funding for the provision of enhanced benefits and services, pharmacy or beneficiary incentives, and resources to support interoperable data exchanges on MTM services. PDPs will have flexibility to design interventions based on their targeted populations and that costs will vary by plan. The PMPM provided by CMS will be based on each enrollee in the plan regardless of the number of beneficiaries participating. The costs associated with this prospective payment will be treated as quality improvement activities for purposes of Part D medical loss ratio requirements.

Performance-Based Payment

An increased contribution by the government of \$2 PMPM amount will be paid in return for a minimum reduction in Medicare expenditures of 2% for care and successful data and quality reporting. The fixed amount is equal to the level of the recent de minimis low-income subsidy amount. This additional payment by the government would also result in a reduction in beneficiary premium payments. Performance payments would be made two years after the completion of the plan year, consistent with the star ratings bonus payment. For example, performance payment for the first year of the enhanced model, 2017, will occur in 2019.

Performance payments will be calculated using a comparison group that meets the same characteristics as the enhanced MTM group, including population, geographic area(s), and participation in the CMMI and non-CMMI initiatives. CMS may also examine PDP's pre-model history expenditures if it improves predictive accuracy. CMS will hire a contractor to conduct the technical assessment and evaluation. This contractor will be revealed to participants prior to the execution of final contracts.

Data Collection and Quality Indicators (pages 9-11)

CMS will develop new MTM-related data and metric requirements for both monitoring and evaluation. CMS will develop quality indicators based on clinical significance and a clear link to improved outcomes. Data and measurement selection will be based upon consultation with CMS subject matter experts and outside organizations, including the Pharmacy Quality Alliance and the Joint Commission of Pharmacy Practitioners (JCPP). Page 11 of the memorandum provides examples of potential measures. CMS also expects PDPs to develop metrics.

Data elements will include specific beneficiary-level interventions and outcomes using standardized Systemized Nomenclature of Medicine (SNOMED) codes. PDPs that submit data inconsistent with strategy, cost, and utilization assumptions approved in the model application will be subject to follow-up by CMS and possibly to requests for corrective actions and compliance actions.

Incentives to Strengthen Communication with Prescribers and Pharmacists

CMS encourages enhancements to interoperable health information technology systems to link PDPs, prescribers, care management teams, and pharmacists to exchange MTM information into workflow systems. According to CMS, this model will complement accountable care organization provider-based clinical management.

Provision of Medicare Parts A & B Data to PDPs (page 12)

Participating PDPs may submit a formal request to receive Medicare Parts A and B data for purposes of improving quality and care coordination. All requests must be in compliance with federal privacy laws.

Applicable Rules, Restrictions, and Waivers (pages 6-7; 16-18)

Waivers from Fraud, Waste, and Abuse Regulations (page 6)

To allow PDPs to carry out the testing models, The Secretary of the Department of Health and Human Services (HHS) may issue waivers from certain fraud, waste, and abuse provisions. Any waivers that are contemplated will be provided in additional communications from CMS and HHS.

Existing Part D MTM Requirements Waived (page 6)

This section grants PDPs the authority to offer MTM services that do not meet the existing Medicare Part D requirements for the target populations and minimum required interventions. This includes the waiver of the requirements that MTM may be furnished by a pharmacist.

Permits Offerings of Supplemental Items and Services to the Clinically-Targeted Population (page 7)

The MTM enhancement is considered an additional benefit, and therefore, requirements for uniformity and accessibility of benefits are waived.

Cost Sharing Reductions to Clinically-Targeted Population Permitted (page 7)

These reductions may only be provided to the clinically-targeted population and not the entire PDP membership.

Reductions in Cost Sharing Counted Toward True Out of Pocket (TrOOP) Costs (page 7)

This is permissible because payment is made on behalf of the Part D beneficiary by an insurance company, group health plan, or third party payment arrangement.

Disclosure (page 7)

Disclosure is waived to the extent necessary to comply with the marketing requirements included on pages 14-15 of the memorandum.

Payment (page 7)

Payment is waived to the extent necessary to permit payments for MTM services as under the model.

MLR Reporting Activities (page 7)

These activities are waived to the extent necessary to allow a PDP sponsor to include in quality improvement activities.

Payments by Pharmaceutical Companies Prohibited (page 16)

PDP sponsors may not in connection with an enhanced MTM program receive funding, in-kind resources, or any kind of payment provided by a drug manufacturer. PDPs may not use pharmaceutical company personnel, manufacturer coupons, or discounts, or manufacturer-supplied materials for this enhanced benefit. To limit the risk of promotion of manufacturer brand name products, PDPs must adhere to the following protections:

- Beneficiary selection may not be based solely on the use of a particular manufacturer or manufacturer products. PDPs must submit protocols for beneficiary selection before implementation.
- PDPs may encourage adherence to brand name products on the formulary that have been previously prescribed and filled at least once by the beneficiary.
- PDPs may recommend a change to a beneficiary's drug regimen (other than generic substitution) when in the interest of the beneficiary.

Provision of Items or Services, and Technology Solutions to Enhance Compliance Permitted Subject to Protocols (pages 16-17)

To provide these services, PDPs must meet the following requirements:

- Specification of the protocol or criteria to be applied before offering the item or service and the criteria for withdrawing the criteria. Withdrawals may be made at the beginning of the plan year and adequate notice must be provided.
- Items or services must be limited to MTM and other related health care purposes
- Information about the MTM program must be explained in direct communication to MTM-enrolled beneficiaries.

CMS Must Approve Protocols and Criteria for Items and Services Delivered by Pharmacies or MTM Vendors (page 17)

CMS is concerned that payments to pharmacies for MTM items and services may result in steering beneficiaries to certain PDPs or that pharmacy recommendations may not be appropriate for the beneficiary. To protect against this, CMS will require that all contracted items and services and protocols for dispensing of these items and services must be approved by CMS. Compensation to physicians is prohibited.

Protecting Against Concerns about Steering Beneficiaries to PDPs Through Cost Sharing Reductions and other Incentives Provided Directly to Beneficiaries (page 18)

To mitigate the risks that plans will steer beneficiaries by providing cost reduction and other incentives to beneficiaries, PDPs must provide the following to CMS:

- Specific protocols or criteria they will apply before offering the incentives and criteria for withdrawing incentives.
- Incentives must constitute a value expected to affect enrollee behavior but not exceed the value of the health related service or activity that the PDP encourages.
- Incentives must be explained directly to MTM-enrolled beneficiaries and not widely marketed.

AMCP's previous comments to CMS on changes to MTM methodology and payment systems

[Comments in response to Center for Medicare and Medicaid Innovations: Request for Information on Health Plan Innovation Initiatives at CMS](#), November 2014

[Memorandum to CMS to Improve MTM Services](#), September 2014

[AMCP Comments to CMS in Response to Medicare Part D Draft 2015 Call Letter](#), March 2014

[AMCP Comments on Request for Information: Evolution of ACO Initiatives at CMS; Section II.B, Integration of Part D Benefits](#), February 2014

If you have further questions about the Enhanced MTM Model Test, please contact Mary Jo Carden, AMCP Vice President of Government and Pharmacy Affairs at ncarden@amcp.org or 70-3684-2603.