Centers for Medicare & Medicaid Services

Center for Medicare and Medicaid Innovation

Medicare Part D Enhanced Medication Therapy Management Model

Request for Applications

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1 Background and General Information

The Centers for Medicare & Medicaid Services (CMS) is seeking applications from Part D sponsors to participate in the Part D Enhanced Medication Therapy Management (MTM) Model. This request for applications (RFA) is open to organizations approved by CMS that sponsor stand-alone basic Medicare Part D Prescription Drug Plans (PDPs). CMS is conducting this model test through the Center for Medicare and Medicaid Innovation (Innovation Center) under Section 1115A of the Social Security Act.

This model will assess whether providing Part D sponsors with additional payment incentives and MTM regulatory flexibilities better achieves the key goals of MTM—i.e., optimized therapeutic outcomes through improved medication use, and reduced risk of adverse events, including adverse drug interactions—while reducing net Medicare expenditures.

If successful, this model will result in PDP sponsors and CMS learning how to "right-size" the investment in MTM services, and identify and implement innovative strategies to optimize medication use, improve care coordination, and strengthen system linkages. In order to accomplish these goals, plans will need to leverage the core competencies of their own organizations, and of their network pharmacy providers, with those of medical prescribers to accurately identify and effectively intervene with all beneficiaries whose issues with medication management have caused, or are likely to cause, adverse outcomes and/or significant non-drug program utilization and costs.

The Part D Enhanced MTM Model is designed to test changes to the Part D program that would achieve better alignment of PDP sponsor and government financial interests and create incentives for robust investment and innovation in better MTM targeting and interventions.

1.1 Scope and General Approach

CMS will implement a Part D Enhanced MTM model test with a five-year performance period that will begin on January 1, 2017 and continue through December 31, 2021. The full duration of the model test will span 7 years, as CMS will continue to make performance-based payments for two additional years after the end of the model performance period. This model will test the impact of granting stand-alone basic PDP sponsors a limited waiver of existing MTM and uniformity and related requirements and of modifying plan financial incentives to encourage Part D plans to offer more targeted and effective MTM services. In evaluating this impact, the primary focus will be on plan and Medicare expenditures, and patient quality of care, satisfaction, and outcomes.

Key elements of this model include:

- Additional regulatory flexibilities to allow for more individualized and risk-stratified interventions
- A prospective payment for more extensive MTM interventions that will be "outside" of a plan's annual Part D bid
- A performance payment, in the form of an increased direct premium subsidy, for plans that successfully reduce fee-for-service expenditures and fulfill quality and other data reporting requirements through this model

CMS will conduct the model test in the following Part D Regions: Region 7 (Virginia), Region 11 (Florida), Region 21 (Louisiana), Region 25 (Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming), and Region 28 (Arizona). Participation in the Part D Enhanced MTM Model is not competitive. CMS will accept all existing Part D sponsors who submit acceptable proposals that meet the model's participation criteria as outlined in this document. All stand-alone basic PDP plans within the test regions that meet the model's participation criteria will be eligible to participate on a voluntary basis, as long as a sponsor who chooses to participate in the model test participates in all test regions in which a qualifying plan is offered each year.

1.2 Statutory Authority

Section 1115A of the Social Security Act (the Act) ((42 U.S.C. § 1315a, added by Section 3021 of the Affordable Care Act) authorizes CMS to test innovative health care payment and service delivery models that have the potential to lower Medicare, Medicaid, and CHIP spending while maintaining or improving the quality of beneficiaries' care (or maintain existing payment levels while improving quality). CMS will exercise this authority here to test this model in the Medicare program.

1.3 Waiver Authority

Under Section 1115A(d)(1) of the Act, the Secretary of Health and Human Services may waive such requirements of Titles XI and XVIII and of Sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) as may be necessary solely for purposes of carrying out Section 1115A with respect to testing models described in Section 1115A(b).

No waivers of any kind are being issued in this document, which merely describes certain waivers contemplated at this time for the model; waivers, if any, would be set forth in separately issued documentation. Thus, notwithstanding any other provision of this RFA, all parties must comply with all applicable laws and regulations, except as explicitly provided in any such separately documented waiver issued pursuant to Section 1115A(d)(1) specifically for the Part D Enhanced MTM Model. Any such waiver would apply solely to the Part D Enhanced MTM Model and could differ in scope or design from waivers granted for other programs or models, or those described below.

Additionally, CMS provides no opinion on the legality of any contractual or financial arrangement that the model participant, its contractors, clinicians, affiliated entities or any other relevant individuals or entities has proposed, implemented, or documented or may implement. The receipt by CMS of any such documents in the course of the application process or otherwise shall not be construed as a waiver or modification of any applicable laws, rules or regulations, and will not preclude CMS, HHS or its Office of Inspector General, a law enforcement agency, or any other federal or state agency from enforcing any and all applicable laws, rules and regulations.

CMS reserves the right to revoke any waiver and suspend model testing at any point.

1.3.1 Payment Rule Waivers

For this model and consistent with the standard set forth in Section 1115A(d)(1), the Secretary intends to waive certain Title XVIII payment-related requirements and their implementing rules to the extent described below, with respect to PDP sponsors' participating stand-alone basic PDPs only.

- **MTM Requirements**

Section 1860D–4(c)(2) of the Act (42 U.S.C. 1395w-104) and the regulatory provision at 42 CFR 423.153(d) would be waived to permit stand-alone basic PDP sponsors to offer MTM services to a model-targeted population that does not meet the definition of "targeted beneficiaries" under Section 1860D-4(c)(2)(A)(ii) and 42 CFR 423.153(d)(2)), and to offer those enrollees an Enhanced MTM program that does not contain the minimum elements and interventions under Section 1860D-4(c)(2)(C) and 42 CFR 423.153(d)(1)(iii, v – vii), all in accordance with the basic stand-alone PDP sponsor's approved programmatic proposal. This includes waiver of the requirement that MTM "may be furnished by a pharmacist" to the extent necessary to test this model, since CMS may approve enhanced MTM programs that include interventions of a type that are not typically furnished by a pharmacist when recommended to resolve all barriers to optimized drug therapy or for financial need.

- **Uniformity and Accessibility of Benefits**

Section 1860D–2(a) of the Act (42 U.S.C. 1395w-102) and the regulatory provisions at 42 CFR 423.104(b)(2) would be waived to the extent a permitted intervention is considered an additional benefit, and not an element of an MTM program, to allow stand-alone basic PDP sponsors to offer supplemental benefits to the clinically-targeted enrollee population, rather than to the entire plan membership.

- **Uniform Cost Sharing**

Section 1860D–2(a) of the Act (42 U.S.C. 1395w-102) and the regulatory provision at 42 CFR 423.104(b)(2) would be waived to permit stand-alone basic PDP sponsors to offer reductions in cost sharing to the clinically-targeted enrollee population, but not to the entire plan membership.

- **Exclusions from Incurred Costs**

Section 1860D-2(b)(4)(C)(ii) of the Act (42 U.S.C. 1395w-102) and the regulatory provision at 42 CFR 423.100 would be waived to permit stand-alone basic PDP sponsors to report and treat reductions in cost sharing (only as approved under this model) as an incurred cost that counts toward the TrOOP threshold, and not as excluded because "the person paying on behalf of the Part D enrollee is […] paying under insurance or otherwise, a group health plan, or third party payment arrangement." This treatment will prevent such amounts from being counted toward plan payments (through Part D reconciliation) while also ensuring that there is no disincentive for either beneficiaries or plan sponsors due to changes in application toward the TrOOP threshold.

- **Disclosure**

Section 1860D-4(a)(1) of the Act (42 U.S.C. 1395w-104) and the regulatory provision in 42 CFR § 423.128 would be waived to the extent necessary for a stand-alone basic PDP sponsor to comply with the model design's unique marketing requirements, or to restrict information solely

to those beneficiaries eligible for Enhanced MTM items and services, according to a plan's programmatic proposal.

- **Payment**

Sections 1860D-13, -15 of the Act (42 U.S.C. 1395w-113, 42 U.S.C. 1395w-115) would be waived to the extent necessary to permit payments for the MTM services in the manner described in this RFA.

- **Minimum Loss Ratio Reporting**

The regulatory requirements in 42 CFR § 423.2430 would be waived to the extent necessary to permit all prospective payments for approved and permissible Enhanced MTM services under the model to be treated as quality improving activities for purposes of MLR reporting requirements.

CMS is not proposing to waive the anti-discrimination provisions of Title XVIII because it does not believe that such a waiver is necessary for the model test. Participating plans are required to implement model interventions in a non-discriminatory manner.

1.3.2 Fraud and Abuse Waivers

For this model and consistent with the standard set forth in Section 1115A(d)(1), the Secretary may consider issuing waivers of certain fraud and abuse provisions in Sections 1128A, 1128B, and 1877 of the Act. As noted above, no fraud or abuse waivers are being issued in this document; fraud and abuse waivers, if any, would be set forth in separately issued documentation. Thus, all parties must comply with all applicable laws and regulations, except as explicitly provided in any such separately documented waiver issued pursuant to Section 1115A(d)(1) specifically for the Part D Enhanced MTM Model. Any such waiver would apply solely to the Part D Enhanced MTM Model and could differ in scope or design from waivers granted for other programs or models.

2 Description of the Model

2.1 Purpose and Concept

Medication Therapy Management (MTM) refers to a variety of activities and resources devoted to optimizing medication use by specific patients. In general, MTM refers to activities intended to optimize therapeutic outcomes by ensuring that patients are taking their medications safely and as prescribed, addressing any barriers to their doing so, and bringing issues to the attention of the treating physician if any changes should be considered. The Medicare Modernization Act (MMA) which created the Part D program requires that every Part D plan offer an MTM program as a quality improvement feature.

However, stand-alone basic Part D plan sponsors' existing incentives may not be well-aligned with the Medicare program's interests in robust quality improvement, i.e., delivery system reform goals of better care, smarter spending, and healthier people. Competitive market dynamics and Part D program requirements and metrics encourage investment in these activities only at a level necessary to meet the minimum compliance standards. Current Part D MTM regulations require uniform service offerings to beneficiaries who meet the plan's program criteria, which must be expressed in terms of numbers of medications and chronic conditions,

and expected annual prescription drug costs. These criteria may both over-identify and under-identify beneficiaries who are either experiencing or at-risk of experiencing medication-related issues and could benefit from MTM interventions. The result is that Part D MTM resources may be misallocated and accordingly fail to support those activities that are likely to have the greatest effect on beneficiary outcomes.

The Part D Enhanced MTM Model is designed to 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.

The primary research questions this model will test are:

- What is the impact of granting stand-alone basic PDP sponsors a limited waiver of existing uniformity and related requirements and providing financial incentives outside of the bid to test innovative MTM interventions?
- What is the impact of MTM interventions on the beneficiary population, on patient outcomes, and customer satisfaction?
- What is the impact of MTM interventions on plan expenditures and on Medicare expenditures?
- What are the market-level impacts?
- What are the effects on plan bids?

2.2 Model Design Elements

2.2.1 Relation to Part D MTM Program

MTM interventions proposed by stand-alone basic PDP sponsors for this model will replace the current Part D program MTM requirements for participating plans. Participating sponsors will no longer submit their standard MTM programs to CMS for approval or include these utilization and cost assumptions in their Part D plan bids. Instead, the sponsor will submit eligibility targeting criteria, interventions, and other program details to the CMS Innovation Center under this model, as well as administrative cost and utilization assumptions for actuarial review. This model will test the impact of providing regulatory flexibility around both targeting and interventions and paying for the administrative costs associated with these MTM interventions outside the Part D bid. All Part D drug costs remain in the Part D bid.

2.2.2 Enhanced and Individualized MTM Strategies

The model features a combination of regulatory flexibilities and payment reform incentives. The regulatory flexibilities will permit stand-alone basic PDP sponsors to risk stratify their enrolled population with respect to medication-related risk and to offer different levels and types of MTM services, as well as cost-sharing assistance for financially needy beneficiaries when this poses a barrier to access, instead of providing the same level to all targeted individuals. Sponsors will also have the flexibility to experiment with alternative documentation (beyond the standardized Comprehensive Medication Review (CMR) format) to improve beneficiary and provider communication and engagement.

The financial incentives will include both (1) a direct (“outside the bid”) prospective payment to stand-alone basic PDPs to support the cost of the Enhanced MTM interventions, and (2) a

performance payment to plans that are successful in improving outcomes and reducing Parts A & B expenditures. The first provides an additional financial incentive for plans to participate, by allowing these plans not to account for MTM-related administrative costs in their bids. The second incentive will take the form of an increased direct plan subsidy (or comparable payment) in future years; therefore, stand-alone basic PDPs whose implementation of this model is successful will be able to offer lower premiums and gain a competitive advantage with potential enrollees.

Under this model, stand-alone basic PDPs can vary the intensity and types of services based on beneficiary risk level, as well as potentially provide certain approved beneficiary incentives to ensure participation. Participating stand-alone basic PDPs could offer higher-risk beneficiaries—those at higher clinical risk, and those most likely to opt out of the MTM program—higher-touch services, such as more frequent person-to-person consultations (whether in the format of CMRs or otherwise) after transitions of care or other changes in risk status. Physicians report that many patients need basic education about the patient's role in how pharmacies, refills, and prescription drug benefits work. Many stakeholders believe that higher-risk beneficiaries may be more effectively engaged with Targeted Medication Reviews (TMRs) performed more frequently than quarterly and delivered person-to-person like a CMR but "in small bites." In contrast to the current approach of an annual CMR, this would allow counselors to assess both medication use and the beneficiary's understanding on an ongoing basis, and to follow up with additional interventions when necessary for the beneficiary and/or prescriber.

While we do not plan to specify either the targeting criteria or the intervention activities that each participating sponsor must offer under the model, we expect that participating sponsors will experiment with and seek out a range of strategies to individualize beneficiary (and prescriber) outreach and engagement for an overall robust and innovative program. Our stakeholder outreach has suggested significant consensus around the reasons for non-optimized medication use. These reasons include a lack of understanding of either prescribing instructions or the reason for the medication, forgetfulness, fear or avoidance of side effects, and/or financial need. Consequently we anticipate that robust programs will include intervention strategies to address these and any other identified barriers to optimized medication use.

Stakeholders also suggested the value of the following strategies in addressing these barriers:

- More varied levels and types of MTM services, targeted at risk-stratified beneficiary characteristics and deploying intervention strategies tailored to the individual's specific barriers to improvement;
- Provider and beneficiary engagement strategies that borrow components from team-based care delivery models, including facilitating delivery of MTM services (physically or virtually) in medical-provider-based settings;
- Greater reliance on local pharmacists to identify at-risk individuals (consistent with plan protocols) and to be authorized and compensated at negotiated rates by the plan for providing targeted counseling and other MTM services at teachable moments and in "small bites";
- Focus on optimized medication use, including facilitating discontinuations of duplicative, inappropriate, or unsafe medications, improving adherence to high-value chronic medication regimens, and ensuring accurate medication administration. Improved accuracy of administration can both improve outcomes and reduce waste, especially for

high-cost drugs where therapeutic goals may not be achieved and expensive regimens may have to be repeated if medications are not taken correctly;

- Greater reliance on clinical pharmacist screening or mediation of communications with prescribers;
- Reliance on prescribers and beneficiaries (or beneficiary caregivers and advocates) to identify at-risk individuals and refer for MTM services —in the case of a physician referral for an MTM pharmacist consult, the beneficiary should understand how MTM fits into the broader coordination of care;
- Allowing prescribers to order medication histories or CMRs in advance of appointments, including annual wellness visits, or medication reconciliations following hospital discharges or ED visits;
- Providing beneficiary medication histories to physicians or other providers in accessible and clinically relevant formats;
- Enabling physicians to order pharmacist consults directly from a standardized list of services on electronic medical record order entry screens;
- Providing physician education, such as on smarter use of antibiotics or on generic or dose optimization alternatives within the prescribed drug class to reduce beneficiary cost sharing amounts;
- Copay assistance when required to eliminate financial barriers for certain financially needy beneficiaries to filling or refilling prescriptions, or taking correct dosage (versus provision of drug samples, which cannot be tracked for drug-drug interactions, adherence algorithms, or to the medication list);
- Facilitating face-to-face, phone, and virtual beneficiary consultations, including in the home environment, to improve access to MTM services;
- Further development of MTM offerings for beneficiaries that fill at least one prescription for a specific medication that is a focus of CMS model tests, such as anti-hypertensives for the Million Hearts™ Initiative, or for beneficiaries with potential overutilization of specific high-risk medications, such as opioids;
- Further development of strategies aimed at preventing and reducing medication-related patient falls, such as those associated with psychoactive or blood pressure medications;
- Development of effective means to acknowledge, track, and measure over-the-counter (OTC) medications to detect and prevent harms that can arise from use of OTC products when combined with prescription medications, particularly cough/cold/allergy treatments, analgesics, and sleeping aids;
- Prospective medication refilling and pre-notification of prescription ordering, or prescription refill synchronization;
- Compliance packaging or smart medication-dispensing devices, and other assistive technology, such as mobile phone or tablet applications to help detect or remove barriers to medication regimen compliance;
- Social support services such as home delivery or transportation needed to obtain prescriptions; and,
- Certain other beneficiary incentives when necessary to incent meaningful care management program participation and behavior change.

2.2.3 Strengthened Linkages with Prescribers and Pharmacists

The Part D Enhanced MTM Model is intended to incentivize strengthened linkages among sponsors, pharmacies, and prescribers. Incentives should be aligned to detect and prevent medication-related risks. In particular, this model may be complementary to ACO-provider-based clinical management, and the combination of the two models will be mutually reinforcing. Prescribers, care management teams, PDP sponsors, and local pharmacists bring different skills to bear on patient medication uses, and have different opportunities for insight and intervention into medication-related issues. Thus stand-alone basic PDP sponsors and subcontracted MTM vendors may involve prescribers and treating physicians in the MTM referral and consultation process, and may establish processes for electronic exchange of interoperable MTM documentation that integrate conveniently into prescriber workflows. Additionally, stand-alone basic PDP sponsors and subcontracted MTM vendors may seek to engage pharmacies more extensively in the MTM process, and may further subcontract certain duties or contract with them to increase beneficiary and prescriber engagement in the MTM process.

2.2.4 Plan Marketing and Member Communications

CMS will limit the pre-enrollment marketing communications that plan sponsors may address to potential enrollees. This restriction is intended to both prevent adverse selection as a result of plan participation in the model and (conversely) to ensure that sponsors do not use participation in this model in a manner that may be misleading or confusing to potential enrollees. More generally, the restriction is consistent with the design of the model, which is not intended to encourage (or discourage) beneficiary enrollment in any specific plan, but instead to give plans additional tools to manage the care of beneficiaries who would have enrolled absent the model.

Sponsors may not feature their participation in this model in marketing materials targeted at potential enrollees. Similarly, unless asked, plan sales representatives may not mention the plan's participation in the model to potential members who have not yet enrolled. CMS will permit participating plans and their representatives to convey truthful and accurate information about the MTM services available through model interventions, but only when a potential enrollee or their authorized representative makes a specific inquiry about them. Such discussions must be accompanied by a disclaimer that indicates eligibility for interventions is not assured and is determined by a plan after enrollment. In addition, a standardized high-level disclosure of the plan's participation in this model will be included in the Evidence of Coverage provided to plan enrollees, the Medicare Plan Finder, and any other public documents or sites where MTM-specific disclosures are required. CMS will also develop scripts for plan sponsors, 1-800-MEDICARE Customer Service Representatives, and CMMI contractors to use in describing model participation.

Once a beneficiary 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 or contain CMS-approved model language. Individualized targeting and intervention strategies are being tested under this model and there are no specific benefits or services that beneficiaries are entitled to receive in the model. 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.

However, beneficiary participation in model activities is always voluntary, and targeted beneficiaries may opt out of offered services at any time. CMS reserves the right to add requirements for beneficiary notices, including use of CMS-approved model language, on a case-by-case basis. In addition, if sponsors indicate in their applications that their beneficiary engagement strategies involve sending out generalized written communications, CMS will require submission for review by the model team prior to use to ensure, among other things, that they are not misleading or confusing, and that they are designed in such a way as to improve health literacy.

2.2.5 Beneficiary Protections

Plans may not under any circumstances increase cost sharing, impede access, or reduce benefits for targeted or non-targeted members. Participating plans are also required to implement model interventions in a non-discriminatory manner. CMS will closely monitor the impact of the model on beneficiaries (see Section 5.2). CMS reserves the right to disallow specific activities in a plan's previously-approved Enhanced MTM program or to terminate a plan's participation in the model at any time if there is evidence to suggest that either a certain activity or the plan's participation in the model is resulting in lower quality care or any other adverse outcomes for beneficiaries.

2.2.6 Sources of Funding

The new prospective payments, or negligible administrative funds from the sponsor's Part D operating margin, are the only sources of funding permitted under the model. Funding from the Part D bid may not be used for the model, nor may the prospective payments under the model be used to fund the sponsor's other Part D program requirements.

Specifically and without exception, stand-alone basic PDP sponsors may not, in connection with an Enhanced MTM program under this model, receive funding, in-kind resources, or any kind of payment provided by a drug manufacturer. Nor may a stand-alone basic PDP sponsor's model make use of personnel affiliated with a manufacturer, manufacturer-financed coupons or discounts provided to a beneficiary, or manufacturer-supplied educational materials. To limit the risk that MTM programs will focus on manufacturer-specific drugs, in particular brand-name drugs, stand-alone basic PDP sponsors will be required to adhere to the following protections:

- Stand-alone basic PDP sponsors may not select beneficiaries for Enhanced MTM based solely on a beneficiary's known use of a particular manufacturer's products or a particular brand drug.
  - Stand-alone basic PDP sponsors will submit protocols for beneficiary selection to CMS for approval before implementation. CMS will review to ensure non-brand or manufacturer-specific related criteria are used.
- Stand-alone basic PDP sponsors may suggest adherence or changes to a beneficiary's course of medication treatment. However, some restrictions are imposed with respect to adherence to drug regimens:

- Sponsors may promote adherence to a brand name drug, but only if the drug is on formulary, and has been previously prescribed and filled at least once by the beneficiary.
- Sponsors may recommend a generic substitution for a previously-prescribed brand name drug; however, any other changes to a beneficiary's drug regimen may be made only when they are in the beneficiary's interest.

2.2.7 MTM Related Items and Services

Beyond the MTM services previously discussed, stand-alone basic PDP sponsors and their MTM-subcontractors may seek to enhance the value of the MTM program by providing additional items and services directly to beneficiaries as appropriate. CMS expects the items could be acquired from technology vendors or network pharmacies, and provided directly to the beneficiary by the pharmacy, or in some cases supplied to the beneficiary directly by the technology vendor at the stand-alone basic PDP sponsor's direction. Examples include assistive devices, such as pill splitters or smart pill bottles, or computer or mobile device applications to reinforce medication regimens.

This introduces the potential risk that items or services could be used by stand-alone basic PDP sponsors as an inducement to beneficiary enrollment in the plan, or an inducement for a beneficiary to remain in the plan to continue receiving the device; or that a stand-alone basic PDP sponsor wishing to encourage the disenrollment of a beneficiary might attempt to arbitrarily withdraw or discontinue the provision of the benefit. To address such risk, CMS will require that stand-alone basic PDP sponsors' intervention plans identify the additional items or services to be provided. CMS will carefully screen for risks highlighted above. In particular:

- Stand-alone basic PDP sponsors must specify the protocol or criteria to be applied before offering the item or service, as well as the criteria for withdrawing the same.
- Stand-alone basic PDP sponsors may not withdraw the MTM items or services as to an individual beneficiary except at the beginning of a plan year (as long as the interventions continue to be necessary and effective), and with adequate notice, if applicable.
- Stand-alone basic PDP sponsors may only offer an item or service if its use is limited to MTM and other related health care purposes, or if other potential uses are incidental.
- The stand-alone basic PDP sponsor may not market the MTM program. The program must be explained in direct communications to MTM-enrolled beneficiaries.

2.2.8 MTM Services Delivered Through Pharmacies

Stand-alone basic PDP sponsors and subcontracted MTM vendors may seek to increase engagement of pharmacies in the MTM process, and may further subcontract certain duties or contract with them to conduct the MTM process. CMS recognizes that pharmacies may be owned by or affiliated with a stand-alone basic PDP sponsor or pharmacy benefit manager (PBM). Pharmacies might be compensated by the stand-alone basic PDP to perform the consultative MTM function. They may also become subcontracted suppliers of assistive devices recommended by the stand-alone basic PDP or MTM vendor. Additionally, pharmacies are situated to provide a unique set of additional appropriate-medication-use-related items or services to beneficiaries that are associated with the dispensing of medication. Those might include home delivery, prescription synchronization, or compliance packaging.

CMS will require that contracted items and services, and the protocols and criteria for the dispensing of items and services, be submitted to CMS for approval regardless of whether they are to be dispensed by a pharmacy or not. At this level of intervention, increased costs incurred for the pharmacy's items and services must be borne by the stand-alone basic PDP sponsor and separately contracted and accounted for in a manner that can be audited by CMS. For instance, such costs must not be transacted for through offsets in the negotiated prices of Part D drugs or other Part D-related fees. CMS will require the stand-alone basic PDP sponsor to establish protocols for pharmacy delivery of items or services and to monitor the pharmacies' compliance.

2.2.9 MTM Services in Cooperation with Prescribers

To increase the potential for success, stand-alone basic PDP sponsors and subcontracted MTM vendors may involve prescribers and treating physicians in the MTM referral and consultation process and may establish convenient data or service ordering processes that integrate conveniently into prescriber workflows. However, compensation to the prescriber is not permitted.

2.2.10 MTM Related Incentives Provided Directly to Beneficiaries

To encourage cooperation with MTM reviews and medication adherence protocols, stand-alone basic PDPs might offer beneficiaries direct incentives, in addition to the additional items and services described earlier. These might include waivers of Part D copayments and other copay assistance for financially needy beneficiaries to promote needed medical assessment and/or follow-up (e.g., for Part B copays for lab tests), or other beneficiary incentives for protocol compliance. These incentives present the potential risk of inducing beneficiaries to enroll or remain in a plan. To mitigate this risk, CMS will require that stand-alone basic PDP sponsors' MTM protocols, submitted in advance to CMS, identify the additional items and services to be provided. CMS will carefully screen for risks highlighted above. In particular:

- The stand-alone basic PDP sponsor must specify the protocol or criteria it will apply before offering the incentives, and the criteria it will apply for withdrawing the incentives.
- The stand-alone basic PDP sponsor must detail the compliance plan it will have in place to ensure that beneficiary incentives are issued in strict accordance with approved protocols.
- Incentives must constitute a value that may be expected to affect enrollee behavior, but not exceed the value of the health-related service or activity the PDP sponsor is intending to encourage.
- The stand-alone basic PDP sponsor may not market the availability of incentives. Incentives must be explained in direct communications to MTM-enrolled beneficiaries.

The provision of certain types of incentives may implicate the fraud and abuse laws. Depending on the facts, an incentive may or may not comply with such laws. Although no waivers of the fraud and abuse laws are being issued in this document, the Secretary may consider issuing such waivers in accordance with Section 1115A(d)(1).

2.2.11 Changes to Model Design in Current Model Year

To increase the potential for success, PDP sponsors who have been approved for participation in the Enhanced MTM model will have the opportunity to submit proposed updates to their approved application narratives with respect to targeting criteria, as well as engagement and intervention strategies, in order to take advantage of lessons learned during implementation. While the prospective payments will not change over the course of a model year, if a participating PDP sponsor believes it can make more effective use of the approved funds through reallocation of resources from strategies that are proving to be less effective than expected to strategies showing greater promise of success, CMS will provide a process for requesting and justifying MTM program updates. Any such updates may not be implemented prior to CMS approval, and CMS reserves the right to restrict PDP sponsors to previously approved MTM programs.

2.2.12 Changes to Model Design in Subsequent Model Years

PDP sponsors that have been approved in Year 1 of the Enhanced MTM model test may make changes to their interventions and cost proposals to be effective at the beginning of each subsequent model year, starting in Model Year 2 (CY 2018). To exercise this option, PDP sponsors must submit a request to CMS, outlining their proposed changes and requesting approval. If sponsors are undertaking new interventions or significantly modifying existing interventions, this request must include supporting information comparable to what would have been required as part of the initial application to participate in the model, such as intervention methodology, clinical rationale, and updated actuarial projections.

For each model year, CMS will set a deadline for organizations to submit modifications to their intervention. In general, this deadline will be sometime in the fall, two years before the model year in question (e.g., changes for CY 2019 would need to be submitted by the fall of 2017, with special procedures for modifying CY 2018 interventions to be issued at a later date). This long lead time is necessary to allow CMS to review and approve any changes well in advance of plan bid submission the following June.

A PDP sponsor may withdraw all of its qualifying plans from the model test by providing advance notice to CMS in accordance with the timeframes applicable to withdrawals from the Part D program. Sponsors may withdraw from participation for subsequent years by written notification by the first Monday in April of the year in which the participation would end. In each case of withdrawal from the model, plans will be required to provide adequate notice to participating enrollees, consistent with current requirements in the Part D program. Sponsors will then be required to submit an MTM program for review and approval per CMS guidance and submission instructions that meets the minimum requirements under Section 1860D-4(c) and 42 CFR 423.153(d).

CMS will retain the right to modify any model policy or parameter on an annual basis, or more frequently in accordance with procedures to be agreed upon in the model's contractual addendum.

2.3 Payment Mechanisms

2.3.1 New Prospective Payments

As part of this model, CMS will offer participating plans a new per-member-per-month (PMPM) prospective payment to provide funding for enhanced items and services, improved system linkages, as well as potentially other pharmacy, prescriber or beneficiary incentives. The PMPM payment will be provided for all plan enrollees, not just those targeted for MTM services. In other words, the costs of the plan's proposed enhanced MTM program will be calculated on the basis of targeted and engaged enrollees, but those costs will then be divided by the plan's total projected enrollment to arrive at the proposed PMPM payment. CMS will fund the costs of the new risk-stratified and patient-targeted interventions in this manner, outside of the plan bids. Plan sponsors will have the flexibility to differentially target beneficiaries and invest in interventions. CMS expects that the actual cost will vary by plan, based on the specific interventions proposed.

Sponsors are required to detail their own specific targeting and cost assumptions in the application, so CMS can evaluate the reasonableness of the targeting and intervention protocols. PDP sponsors must respond to the RFA with sufficient specificity for CMS to understand the proposed MTM intervention plans in detail. CMS will assess sponsors' performance with respect to their approved model intervention plans through review of plan-submitted data (see Section 5.1). CMS reserves the right to request that plans modify their cost assumptions as part of the review of model proposals. Actual PMPM prospective payment amounts will be based on the cost assumptions embedded in participating plans' approved applications. CMS will not adjust these prospective payment amounts for actual expenditures, but will permit submission of annual updates, and will require at least annual cost reporting. The Enhanced MTM PMPM would be submitted for approval and paid in each year of the model and may be updated on an annual basis. The MLR regulatory requirements would be waived to the extent necessary to permit all prospective payments for approved and permissible MTM services under the model to be treated as quality improving activities for purposes of MLR reporting requirements.

2.3.2 New Performance-Based Payments

Starting in Year 3 (2019), CMS will also offer a performance-based incentive payment in return for a minimum reduction in Medicare costs of care and successful data and quality reporting. The incentive will be set at a fixed $2.00 per-member-per-month amount, which is equal to the level of recent Low Income Subsidy benchmark de minimis amounts. This performance-based payment will be in the form of an increase in government contribution to the plan premium, i.e., as an increase in the direct subsidy component of Part D payment (or an equivalent payment). The plan would still receive the total payment specified in its bid, not an additional add-on payment. However, the government-funded portion of the monthly bid would increase, and the beneficiary portion (premium) would correspondingly decrease for all plan enrollees. Thus, plan sponsors will submit standardized bids as usual based on their cost requirements, and then any additional premium subsidy earned will be subsequently applied to the plan premium prior to its inclusion in CMS low-income subsidy (LIS) premium calculations. In other words, the premium reduction will be considered in determining the low-income premium benchmark.

Performance results in model Year One (2017) will be used to determine eligibility for a performance-based payment in Year 3 (2019). Year 3 would be the first year in which sponsors

could receive a performance-based payment under this Model. This timing would be similar to the lag in the Part C&D Star Ratings effect on Medicare Advantage quality bonus payments. Similarly, performance results from model Year Two (2018) would determine eligibility for the performance-based payment in model Year Four (2020), and performance results from model Year Three (2019) would determine the performance-based payment in model Year Five (2021). If earned in model Years Four and Five, the performance-based payments would be applied in Years Six (2022) and Seven (2023) after the end of the model performance period.

Eligibility for the performance payment incentive will be calculated based on reductions in Parts A and B costs net of model prospective payments. This encompasses all Medicare expenditures for model enrollees, with the exception of ordinary (non-model) Part D costs. CMS is setting a minimum savings rate of 2% in order to qualify for the performance payment.

In order to calculate savings, Parts A and B Medicare expenditures for enrolled beneficiaries in the intervention year will be compared to a performance-payment benchmark, which will be determined based on expected Medicare costs. Savings will be calculated across all beneficiaries enrolled in a participating plan, whether or not they are targeted for Enhanced MTM services. To calculate the performance-payment benchmark, CMS will apply a process as follows. The plans will be benchmarked to a comparison population that is selected based on a statistical matching methodology. The comparison group will be similar to the intervention group (enrollees in the participating plan) in terms of population characteristics, geographic characteristics, and participation in the CMMI and non-CMMI initiatives. The final performance-payment benchmark will take into account other initiatives and changes in Medicare payment policy during the model's performance period. It may also make use of participating plans' pre-model historical expenditures, if this is found to improve predictive accuracy. In other words, the performance-payment benchmark is the expected aggregate Medicare Part A and Part B expenditure for a participating plan's beneficiaries had the plan not participated in the model. Precise parameters for calculating the performance-payment benchmark will be determined by CMS at a later date, and will be shared with participating plans prior to their signing a final participation agreement.

In addition to meeting savings requirements, plans must successfully report all required model data elements in the manner and format specified by CMS in order to qualify for the performance payment. As a measure of substantive progress, CMS will require that by the end of Year 3 participating plans generate annual savings at least as great as the total annual value of model prospective payments in that year or face model termination. CMS may also consider introducing minimum quality performance standards or other pay-for-performance elements in future model test years, or as part of a potential model expansion.

2.4 Applicant Eligibility and Participation Requirements

2.4.1 Geographic Scope

Stand-alone basic PDP sponsors that choose to participate in the Part D Enhanced MTM Model must participate in all model test regions in which they offer a qualifying plan. CMS will test the model in five (5) of the thirty-four (34) existing (U.S.) Part D Regions, specifically:

- Region 7 (Virginia)
- Region 11 (Florida)

- Region 21 (Louisiana)
- Region 25 (Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming)
- Region 28 (Arizona)

Using a process driven by objective criteria and random generation of potential test cohorts, CMS selected this set of regions to allow for a sufficiently powered model test with comparison regions and to be (in aggregate) broadly representative of national market characteristics. Regions were evaluated based on variation in market competition, the range of geographic, population, and market characteristics, and the range of Parts A&B spending variance. We grouped regions based upon characteristics that would maximize generalizability of results to a national population, e.g., geographic diversity, population size, number of Part D plans, and enrolled populations. Then we randomly generated combinations of test states that, as a group, met analytic and administrative requirements that increased the odds of a successful model test.

2.4.2 Plan Eligibility

In order to participate in this model, a plan must:

- Be an individual market standalone basic plan
- Have a minimum enrollment of 2,000
- Have existed as a basic plan for at least three years prior to first year of the model test
- Not be under sanction by CMS or law enforcement entities, such as the OIG

The requirement to be a basic plan ensures that eligible plans will have similar enrolled populations with a wide variation in risk (as opposed to non-basic "enhanced" plans that attract a disproportionately healthy population due largely to the exclusion of LIS auto-assignees and diminished availability of premium subsidies for dual eligible beneficiaries). These plans will have the largest proportions of beneficiaries who are most in need of improved care coordination and the identification and removal of barriers to optimized medication use. The minimum enrollment size (at the time of plan selection, i.e., in mid-2016) ensures that there can be sufficient statistical power for meaningful evaluation of changes in predicted outcomes to be reliably measured. The three-year history prior to the first year of the model test (since the 2014 coverage year) ensures that CMS has had time to monitor and evaluate the sponsor's ability to implement and comply with Part D requirements.

All plans within the test regions that meet the plan eligibility criteria and have a Part D summary score of three stars or higher will be eligible to participate on a voluntary basis. Plans with a summary score of less than three stars will be considered on a case-by-case basis. Any plan with a Part D summary score below three stars will be required to provide additional documentation in order to participate in the model. Specifically, any such plan must justify how its model participation would align with the CMS quality strategy and support its efforts to improve its quality performance. Any such plans approved to participate in the model may also be subject to additional monitoring requirements, and should consider their participation in the model probationary. The above requirements apply to plans applying to participate in the model, and plans that see their quality scores drop during the course of model implementation. The ultimate decision on the plan's participation in the model would be at CMS's discretion, based on the best interests of the Medicare beneficiaries. CMS does not expect to allow plans that have scored

below three stars in three consecutive years, and have therefore earned a low-performing icon to participate in the model.

A plan sponsor may exit the model after the completion of any one year, but none may join after the first year.

2.4.3 Target Population

Plan sponsors are not required to limit interventions to pre-defined beneficiary categories, but are required to submit written plans for their proposed protocols outlining how they will target beneficiaries. CMS expects plan sponsors will likely choose to prioritize beneficiaries with the following types of indicators:

- Chronic diseases where treatment and outcomes are highly dependent on medication (e.g., diabetes, CHF, COPD, asthma)
- Transitions of care
- Polypharmacy combined with multiple prescribers
- Frequent recent utilization of heath care services
- Lack of social supports
- First fills of certain drugs with difficult side-effect or complication profiles

CMS and plan sponsors exchange enrollment data through the CMS Medicare Advantage Prescription Drug System (MARx). CMS expects to modify this system so that participating plans can prospectively submit new coding in order to report beneficiary eligibility, model "enrollment" dates, and status in the model. Such transactions will be submitted through MARx to the Medicare Beneficiary Database (MBD) or other specific CMS beneficiary data system of record where it would be stored.

3 Medicare Data Sharing with PDP Sponsors

CMS will provide participating sponsors the opportunity to request their enrollees' Parts A&B claims data, in order to see the fee-for-service medical services a member has received and to provide greater context for each beneficiary's medication regimen. To assist participating sponsors in creating improved linkages with integrated care management teams, CMS may also provide access to beneficiary alignment with integrated care models, such as the ACO alignment records managed in CMS' Master Data Management (MDM) system.To receive access to the data, participating sponsors will have to submit a formal request for the data that indicates they are requesting the beneficiary identifiable claims data for their own health care operations purposes as covered entities, and the data reflects the minimum necessary for the sponsors to conduct those health care operations, consistent with 45 C.F.R. § 164.506(c)(4). CMS will provide instructions on how approved model applicants can submit these requests and execute data use agreements via an electronic process at a later date. CMS will endeavor to provide timely data as requested.

4 Learning and Diffusion Resources

The goals of a model learning system are to support the testing of new practices, actively measure progress, and facilitate sharing of non-proprietary breakthrough ideas that can accelerate progress in a competitive market. CMS will support stand-alone PDP sponsors in accelerating their progress in the model test by providing them with opportunities to both learn about best practices in achieving performance improvements and to identify topics of mutual interest to model participants for collaborative learning events. This will be accomplished through a learning system that will use various group learning approaches to help stand-alone PDP sponsors effectively share experiences, track progress, and rapidly adopt new methods for improving quality and efficiency. CMS expects stand-alone basic PDP sponsors and participating plans to actively participate in the learning system by attending periodic conference calls, topic-specific affinity groups, webinars, annual face-to-face meetings, regional face-to-face meetings and progress reporting through an online platform.

Participating sponsors will also be required to develop and implement their own internal (sponsor-specific) learning systems that will support the collection, evaluation, and dissemination of sponsor (or plan-specific) lessons learned on the effectiveness of interventions to beneficiaries, prescribers, pharmacists, and other stakeholders. Sponsors will be required to periodically share information on their internal learning systems with CMS.

5 Quality and Performance Monitoring

CMS believes that programs that actively self-evaluate will have the greatest opportunities for improvement in quality and reductions in overall healthcare costs. Stand-alone basic PDP sponsors will be required to collect and produce data and analysis of the model interventions that will be shared with CMS and its contractors. In addition to this self-monitoring and self-evaluation, CMS will also collect from awardees a standard minimum set of data elements (see next section) with which to compile performance indicators through its monitoring and evaluation contractors. Precise specifications for data collection will be determined with the assistance of a technical contractor and an evaluation contractor, as well as public comment. Stand-alone basic PDP sponsors are required to provide the requested data to CMS and its contractors for purposes of monitoring and evaluating the model, in accordance with 42 C.F.R. § 403.1110.

Collected data may include the following types of performance indicators:

- Number of engaged pharmacists and providers
- Number of prescriber patient referrals
- Number of engaged patients
- Number of identified individuals at risk of medication-related issues
- Number of clinically significant risks targeted
- Number of missed opportunities
- Number of follow-up touch-points/interventions
- Number of refill synchronizations
- Number of transition of care medication reconciliations

- Number of copay reductions or waivers
- Number of assistive devices or applications

Furthermore, CMS will require retrospective cost reporting in combination with results measurement and "lessons learned" narrative descriptions from the sponsors' internal learning systems. Any sponsor that submits data that are substantially inconsistent with the strategies, costs, and utilization assumptions approved in the model application will be subject to follow-up by CMS and possibly requests for corrective or other compliance actions. The contract addendum for participation in this model will incorporate CMS's existing contractual compliance mechanisms to enforce compliance.

5.1 Data Collection and Quality Indicators

CMS will develop new MTM-related data and metric collection requirements for both monitoring and evaluation purposes, which plans will be required to meet as a condition of model participation. Key principles in developing quality indicators will include (1) clinical significance, and (2) a focus on process measures with a clear link to improved outcomes. CMS will aim to develop initial detailed data collection and validation specifications by mid-2016. Potential quality indicators may include (but are not limited to) the metrics under consideration by the Pharmacy Quality Alliance (PQA) and the Joint Commission of Pharmacy Practitioners (JCPP).

A uniform set of data elements to be collected will include records of specific beneficiary-level interventions and outcomes, which we refer to as MTM encounter data. We expect that the clinical activities in these encounters will generally be identified through the use of Systematized Nomenclature of Medicine (SNOMED CT) codes. SNOMED CT codes are a list of value sets owned and distributed by the International Health Terminology Standards Development Organization. SNOMED codes are not currently widely used, but can be used to represent clinically relevant information consistently and reliably. This coding provides a standardized way to represent clinical phrases captured by the clinician and enables automated interpretation.

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 certain quality indicators, and for model evaluation.

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.

In general, CMS expects that model data submission requirements and quality metrics will need to be developed collaboratively with key stakeholders, including participating stand-alone basic PDP sponsors. All relevant stakeholders will have an opportunity to comment and provide feedback before any decisions on these topics are finalized.

5.2 Monitoring and Oversight

CMS will closely monitor model implementation, to ensure that model interventions are consistent with model rules and plan proposals, that additional model funding is being used for the appropriate purpose, and that the model is not leading to any adverse beneficiary outcomes. CMS will have the right to terminate a plan's participation in the model at any time if it is violating model terms and conditions, or if there is evidence that its participation is leading to adverse patient outcomes or resulting in any other serious unintended consequences. CMS will reserve the right to (1) impose a corrective action plan as a condition of continued participation or (2) terminate a participating organization from the model test to rectify or address a failure to adhere to model requirements, or to make substantial progress towards improving its MTM program and generating savings.

CMS will closely monitor the impact of the model on beneficiaries. This will include, but not necessarily be limited to, observing existing metrics of beneficiary access, outcomes, and satisfaction, and monitoring of increased beneficiary questions or complaints through 1-800-MEDICARE or the Medicare.gov website. CMS reserves the right to investigate any participating plan if it has reason to believe the plan's participation in the model may be adversely affecting beneficiaries.

6 Evaluation

CMS will use an independent contractor to conduct an evaluation of this model. The evaluation will examine how the model was implemented by the MTM model participants and assess the model's impacts on enrollees and the factors that contributed to those impacts. All MTM model participants will be required to cooperate fully with CMS and its evaluation contractor. Cooperation with the evaluation efforts may include participation in surveys, interviews, site visits, direct observation of patient interactions, and other activities that CMS determines necessary to conduct a comprehensive formative and summative evaluation. In addition, CMS and its contractors may use data or information submitted by the MTM model participants for quality and monitoring purposes (see above). MTM model participants will need to ensure that all written agreements, consents, and/or legal relationships have been secured that are necessary to ensure that CMS and its contractors can carry out evaluation activities.

7 Application Process and Selection

PDP sponsors are required at the time of application to specify the plans they will enroll in the model test, and the regions in which those plans will participate. Although participation is voluntary, a PDP sponsor that chooses to participate in the Enhanced MTM model test must participate in all test regions in which it offers a qualifying plan.

PDP sponsors must respond to the RFA with sufficient specificity for CMS to evaluate and understand the proposed MTM intervention plans in detail. In general, CMS will review applicants' proposed interventions and justifications to ensure that they are clinically and operationally plausible, are consistent with the utilization assumptions in the actuarial estimates, and are not likely to lead to adverse or unintended consequences. CMS reserves the right to negotiate with applicants and request submission of application updates as part of its review of Enhanced MTM intervention plans.

Applicants are required to respond in a narrative format, describing their MTM intervention plans in detail, e.g., the new targeting criteria, outreach, engagement, and intervention strategies, as well as their assumptions concerning opt-in rates, theories of action, and outcomes. CMS will also require preliminary actuarial estimates of the cost and utilization assumptions associated with these populations and interventions.

As part of the application, applicants will be required to provide the following information:

- Basic plan information, including contract ID, plan ID number(s), along with the names, titles, and contact information for key plan staff responsible for implementation of the model.
- A narrative description of the targeting criteria the plan intends to utilize along with estimates of how many plan enrollees fall into each category of criteria.
- A narrative description of the outreach and engagement strategies the plan will utilize to achieve enrollee participation and expected participation rates.
- A narrative description of the specific intervention(s) that the plan intends to utilize and how such strategies would be expected to yield improvements in quality and/or cost savings; in other words, the mechanism by which the plan expects outcomes will be affected, the goals it will set, and how it will measure progress towards goals.
- An outline of all the types of individuals and entities involved in the applicant's enhanced MTM program implementation and delivery, including all associated payment flows among those entities contracted to provide or support MTM interventions.
- A projection of the per-member-per-month (PMPM) cost of the plan's proposed interventions certified by a Member of the American Academy of Actuaries.
- If applicable, a narrative description of the process and criteria for assessing and applying cost sharing assistance.

In both the narrative and cost assumptions of the application, CMS expects to see variations in the intervention strategies, as well as different outreach and engagement strategies aimed at segments of the target population with varying clinical, cultural, and socioeconomic characteristics. One-size-fits-all approaches to targeted beneficiary outreach will not be considered sufficient to significantly increase engagement in effective MTM program activities. CMS expects to see protocols involving multi-pronged, proactive, and persistent efforts to recruit Medicare beneficiaries and ensure their on-going participation and engagement, as well as use of diverse communication modalities such as person-to-person interactions, phone calls, and trusted community contacts and relationships (community pharmacists and prescribers) to achieve significant engagement rates. A satisfactory review of the assumptions behind the engagement rates is central to CMS approval of a plan's proposal.

Any applicant with a contract that has 2016 Medicare Star Ratings with a Part D summary score less than 3.0 must also provide a detailed narrative description of how participation in the Enhanced MTM model test will align with the CMS quality strategy and support the PDP sponsor's efforts to improve its quality performance. This response must specifically address the theory of action and expected impacts on all individual measures with less than a 3.0 score. CMS will review these responses for the reasonableness of approach, adequacy of timing and resources, and clinical plausibility of proposed results. Any such plans approved to participate in the model may also be subject to additional monitoring requirements, and should consider their participation in the model probationary. The above requirements apply both to contracts applying to initially participate in the model, and contracts that see their quality scores drop during the course of model implementation. CMS will issue guidance on how to submit this information at a later date.

In order to align cost proposals with final data submitted with the Part D bid, e.g., with projected enrollment numbers, CMS may require submission of a proposal update in or around July of each year.

7.1 Questions

Questions regarding the Part D Enhanced MTM model or application process may be sent by email to EnhancedMTM@cms.hhs.gov. CMS may publicly share responses to questions on the Innovation Center website to ensure that all applicants have access to clarifying information regarding the model and the application process.

7.2 Accessing the Online Application Portal

Interested organizations must apply to participate by responding to this RFA through the online application portal. CMS will communicate instructions for accessing the online application portal through the CMS HPMS system. Stand-alone basic PDP sponsors will be able to use the online portal to submit applications electronically. The online portal will include instructions for electronic signing and instructions for uploading any supplemental material electronically. Appendix A contains a template of the application questions that stand-alone basic PDP sponsors will respond to through the online application portal.

7.3 Deadline for Application

The deadline for receipt of applications in response to this RFA is 4:00 PM EST on January 8, 2016. Proposals in response to this RFA must be complete and submitted using the online portal before the deadline.

7.4 Model Selection and Contracting

7.4.1 Selection

Model participant selection is not competitive. CMS expects to see variations in the intervention strategies proposed by plan sponsors, as well as different outreach and engagement strategies aimed at segments of target populations with varying clinical, cultural, and socioeconomic characteristics.

CMS wishes to maximize participation in this model test and will admit all interested stand-alone basic PDP sponsors that apply to the model test before the deadline for receipt of applications, provided the stand-alone basic PDP sponsor and its proposed participating plan meet CMS's participation criteria, and the stand-alone basic PDP sponsor's proposal is acceptable to CMS based on the likelihood that the interventions proposed will yield improvements in quality and/or cost savings. The intervention plans in the applications will be reviewed to make a reasonableness assessment of the likelihood that the level and type of interventions proposed will yield improved results and will be robust and comprehensive enough to potentially achieve targeted cost reductions in Medicare Parts A and B expenditures. The actuarial estimates will be reviewed by CMS (and an actuarial services contractor) to identify any significant concerns that warrant additional scrutiny and/or revision.

In general, CMS will review applicants' proposed interventions and justifications to ensure that they meet a minimum threshold of clinical and operational plausibility, are consistent with the utilization assumptions in the actuarial estimates, and are not likely to lead to adverse or unintended consequences. Proposed interventions that fail to meet this standard will not be approved.

During the model selection process, CMS will conduct program integrity screening and may decline to select otherwise qualified applicants on the basis of information found during a program integrity screen. Further, CMS reserves the right to reject any organization, plan or proposal on grounds required to preserve the integrity of the Medicare program, the welfare of beneficiaries, or the administration of the Part D Enhanced MTM Model.

In accordance with Section 1115A(d)(2) of the Social Security Act, there is no administrative or judicial review of the selection of organizations, sites, or participants to test models.

7.4.2 Contracting

CMS will formally obligate participants to the terms of the model test via a model-specific supplemental addendum to their current agreement with CMS for participation in Part D. That contract addendum will incorporate the participant's programmatic proposal, as well as any policy documents issued by CMS to govern the model test. CMS expects to enter into final addenda in September 2016 concurrently with the signing of other Part D contract documents.

Participating stand-alone basic PDP sponsors will execute Part D contract addendum agreements that will include terms and conditions that vary from standard Part D requirements, such as:

- Applicability of specific waivers of regulatory or statutory requirements, and any limitations to such waivers
- Prohibition on limiting medically necessary services
- Prohibition on increasing cost sharing above levels in the approved benefit package
- Prohibition on payments to entities except those outlined in the approved application
- Prohibition on locking beneficiaries into use of specific pharmacies to receive Enhanced MTM services
- Requirement for regular periodic reporting of beneficiary enrollments and beneficiary encounter-level interventions using data formats and transmission protocols specified by CMS

- Requirement for retrospective reporting on actual costs of model
- Requirements for participation in CMS Innovation Center learning and diffusion activities, for sharing quality and performance monitoring data, and for cooperating with CMS monitoring and evaluation activities

Commencement of participation in the model may be conditioned on criteria to be specified at a later date, such as a successful readiness review, approval of policies, and review of communication materials. CMS may also require approved participants to submit updates to their plans on an as-needed basis.

CMS will retain the right to modify any model policy or parameter on an annual basis, or more frequently, in accordance with procedures to be agreed upon in the model's contractual addendum.

CMS will reserve the right to impose a corrective action plan as a condition of continued participation or to terminate a participating organization from the model test to rectify or address a failure to adhere to model requirements, or to make substantive progress towards generating savings. Short of termination, failure to promptly implement corrective action and resolve CMS concerns could result in disapproval of those model design elements from which the noncompliance arose and/or reduction of prospective payment amounts. Further, an organization's failure to adhere to the requirements of the model test may result in rescission or invalidation of a waiver applicable to that organization, which could trigger enforcement action by CMS related to the waived requirements. All other regulatory and statutory requirements applicable to the organization's stand-alone basic PDP plan will remain in effect. Failure by an organization to comply with those requirements could result in enforcement action consistent with the authority of the Part D program, including intermediate sanctions or contract termination.

7.5 Timeline

Table 1 contains a summary timeline for Part D Enhanced MTM Model RFA and participant selection as part of the calendar year 2017 Medicare Part D bidding and contracting processes

Table 1. 2017 Enhanced MTM Model Application Milestones

Date	Milestone
January 2016	• Model Applications Due to CMS
March 2016	• Provisionally Selected Model Plan Participants Identified
July 2016	• Model Application Update Window
July/Aug 2016	• Model Agreements Released to Plan Participants
September 2016	• Model Agreements Fully Executed (after Part D contracts)
January 2017	• Prospective Payments to Participating PDPs Begin
January 2017	• Model Year 1 Performance Period Begins
June 2017	• First Quarterly Monitoring Report on Expenditures and Utilization

7.6 Withdrawal of Application

Applicant organizations seeking to withdraw an entire application or modify a pending application should submit a written request on the parent organization's letterhead that is signed by the primary point of contact named in the application submission. To submit a withdrawal request, applicants must send the request in a PDF format by email to EnhancedMTM@cms.hhs.gov.

The following information must be included in the letter:

- Legal Name of the Parent Organization
- Address and Point of Contact information named in the application
- Exact Description of the Nature of the Withdrawal (e.g., Withdrawal of entire application or change in selected markets)

7.7 Amendment of RFA

CMS may modify the terms of the Enhanced MTM model test or cancel it entirely in response to stakeholder comments or other factors. The terms set forth in this RFA may differ from the terms set forth in the final addendum for participation in the model test.

Appendix – Application Template

This Appendix details the information and certifications applicants must provide to CMS through the online application portal. Applicants will also be required to provide contact information and other like information. CMS will release instructions for use of the online portal at a later date. CMS may revise the information below.

Tab 1: General Information

1. Please provide a narrative introduction to your proposed Enhanced MTM for robust investment and innovation in better MTM targeting and interventions. This response should not describe the specifics of your proposed program. Rather, this is an opportunity for a general overview of your proposal, which you will detail later in this application. The description should address:
    1. Principles guiding your approach to Enhanced MTM;
    2. Anticipated effects of Enhanced MTM;
    3. Organizational experience with Enhanced MTM (or similar programs) in other lines of business;
    4. Integration of Enhanced MTM into other current or anticipated disease management and enrollee health improvement programs;
    5. Strategy for communication of Enhanced MTM interventions to eligible enrollees, including those with socio-economic barriers to participation;
    6. Strategy for communication with eligible enrollees' medical providers;
    7. Internal policies and procedures for protecting the interests of enrollees during the model test;

8. Internal measures you will employ for tracking the success or failure of the proposed interventions.

Tab 2: MTM Programs

In this section, applicants must detail the specific Enhanced MTM-related items and services to be made available to targeted enrollees. Each combination of programmatic criteria and strategies that differs at the plan (plan benefit package) level must be separately identified and described. If information is repeated from one strategy or enrollee group to another, do not refer back to the first plan or enrollee group. Rather, information should be restated in the correct location, even if verbatim. If one set of Enhanced MTM criteria and strategies will be employed in a uniform manner across all of the sponsors' participating plans, then applicable regions should be designated as "ALL" and one set of responses may be submitted.

2. For your selected combination of plan(s) and Enhanced MTM program, please specify:
    1. Plan number(s)
    2. Applicable Region(s)
    3. Provide a clear, detailed description of targeting criteria, expected prevalence in enrollee population, methodology for identification, and responsible party (who will be conducting the targeting).
        i. If targeting will be conducted on the basis of specific diagnostic, procedural or drug coding, please provide detailed lists of those codes.
        ii. Provide a clear, detailed description of additional specific model features that will be in place to ensure that targeted enrollees understand the voluntary nature of MTM interventions.
    4. Provide a clear, detailed description of means of communication utilized to contact and engage targeted beneficiaries in this group, including multiple levels and strategies for contact to address sequential attempts (and the sequential steps that will be used), and different scenarios, e.g., to reach individuals with cognitive issues, language and/or cultural barriers.
        i. If generalized written communications are employed in outreach or engagement processes, provide a description of the intent, distribution triggers, and distribution methodology. CMS may require submission of sample documents at a later date.
        ii. Please describe your protocols for ensuring that all communications facilitate beneficiary involvement in health care decisions and improve health literacy.
    5. Provide a clear, detailed description of the means by which targeted enrollees are motivated to participate in MTM activities, and assumptions about your effective engagement rate (% targeted that do not opt out, explicitly or implicitly, and accept/participate in MTM interventions). This description will include both the (a) initial acceptance and (b) continued interaction between the targeted beneficiary and the operator following the initial acceptance. Your engagement rate can be defined at

a uniform aggregate targeted population level, or by targeted segment, if variation by segment is predicted.

6. Provide a clear, detailed description of the specific MTM items or services to be provided (or contracted for) and how these will be deployed to address specific enrollee barriers to safe and appropriate medication use (what, who, when, where). If any of the items or services will be differentiated by target population, please explain why and how.
    i. For any items or services that would reasonably be expected to continue over time, please describe the triggers and process for discontinuing the items and services, including the timing and general content of any notices.
7. Provide a clear, detailed description of your goals for the expected impact on quality and costs with clinical rationale (how). Your description should include expectations about the direction and degree of project impact on CMS Star Rating metrics and medical service utilization.
8. Provide a clear, detailed description of additional internal outcome metrics that you will track to assess progress toward goals, including impacts on quality and costs.
9. Provide a clear, detailed description of internal learning and diffusion practices the plan will implement to monitor and implement lessons learned.
10. If interventions for this group include cost sharing assistance for financially needy beneficiaries, please provide a clear, detailed description of proposed cost sharing assistance protocols:
    i. Provide a clear description of how cost sharing assistance will be used to address financial need barriers. Your description should include specifics on the types of drugs, items, or services for which you will consider providing cost sharing assistance and an explanation of how this use of funds is directly related to proper use of the medication.
    ii. Provide a clear description of the protocols to be used to determine enrollee need for cost sharing assistance.
    iii. Provide a clear description of the process for triggering any changes in and/or for discontinuing cost sharing assistance.
    iv. Provide a clear description of the process for providing the cost sharing assistance to the enrollee, or other service provider, if applicable.
11. Provide a clear, detailed description of other proposed enrollee incentives and protocols:
    i. Provide a clear description of the additional proposed enrollee incentives.
    ii. Describe in detail the criteria and protocols used to provide the incentive to an enrollee.
    iii. Provide a clear description of the process for triggers and discontinuing the additional enrollee incentives
    iv. Describe in detail the internal controls you will have in place to ensure that beneficiary incentives are issued in strict accordance with plan protocols.

12. Provide a clear, detailed description of all potential payment flows between sponsor and other parties included in MTM program design including those contracted to provide or support MTM interventions.
13. Provide a clear, detailed description of the actions you will take to include meaningful prescriber involvement in MTM services, including strategies to improve the value of actionable information provided, involvement in referrals or consultation process, or other linkages with prescriber workflows.
14. Provide a clear, detailed description of the actions you will take that support the goals of the Office of the National Coordinator for Health Information Technology (ONC's) Shared Nationwide Interoperability Roadmap in designing and implementing the model, including promoting better connectivity and coordination between health care providers in different settings, and refining and advancing the HIT standards for electronic interchange of information on MTM services.
15. Provide a clear description of any Medicare data on your enrollees you believe you will need to conduct your MTM program, and how you would utilize and protect the privacy and security of this information, if received from CMS.
16. Do you wish to enter a different Enhanced MTM program for another plan?

Tab 3: Applicant Suitability

3. Applicant must identify any investigations, probations, sanctions, penalties, or corrective action plans against the PDP sponsors offering the plans identified in this application, its owners or managers, including any sanctions or corrective actions imposed while participating in prior CMS demonstrations and programs (if applicable). Applicants must identify the foregoing information from January 1, 2010 until the present.
    1. Does applicant have any information to identify (y/n)?
    2. If so, provide a clear and detailed description of the information.
    3. Does the applicant's PDP contract have a current (2016) Medicare Star Ratings Part D Summary Score below 3.0?
    4. If so, please provide a detailed narrative description of how participation in the Enhanced MTM model test will align with the CMS quality strategy and support the PDP sponsor's efforts to improve its quality performance. Your response must specifically address the theory of action and expected impacts on all individual measures with less than a 3.0 score in the most recent annual Medicare star ratings.

Tab 4: Actuarial/Financial Documentation

Upload all required actuarial or financial documentation here, including your prospective payment proposal with utilization and unit cost assumptions. A separate submission will be required for each different Enhanced MTM program described in Tab 2. CMMI will provide additional guidance on the submission of actuarial or financial documentation.

Do not upload other materials. Other materials can be uploaded on the following screen.

Tab 5: Supplemental Information

Upload any additional materials. Additional materials might include supplemental statements if more space is needed to complete a question, or graphic items like charts and tables. Do not upload actuarial or financial documentation here.

Tab 6: Applicant's Certification

By clicking below <<Name of user>> agrees on behalf of the applicant PDP sponsors that:

1. The information contained in the application is true, correct, and complete as of the date it is submitted to CMS. If applicant becomes aware that any information in this application is not true, correct, or complete, applicant will notify the Centers for Medicare & Medicaid Services (CMS) immediately and in writing.

2. Applicant authorizes CMS to verify the information contained herein, including inspecting the premises of the applicant's organization or plan to ensure compliance. Applicant shall notify CMS in writing of any changes that may jeopardize applicant's ability to meet the requirements of the Enhanced MTM model test prior to such change or, if prior notification is not feasible, no later than 30 days after the effective date of such change. Applicant acknowledges that such a change may result in revocation of approval of any element of this application issued by CMS, or termination from the enhanced MTM model test.

3. Applicant and <<name of user>>, submitting the application on applicant's behalf, understand that in accordance with 18 U.S.C. §1001, any omission, misrepresentation or falsification of any information contained in this application or contained in any communication supplying information to CMS to complete or clarify this application may be punishable by criminal, civil, or other administrative actions including revocation of approval, fines, and/or imprisonment under Federal law.

4. Applicant acknowledges that operational policy guidance relevant to this application is or may be posted on the CMS website, and that it is continually updated. Applicant will agree to comply with such guidance, as applicable, should applicant be approved to participate.

5. Applicant agrees that until such time as it is accepted to participate in the Enhanced MTM model test and bound by the terms of a model-test-specific addendum to its contract for participation in Part D, it shall abide by the following terms and conditions:
    a. Applicant will not advertise its participation in the Enhanced MTM model test or market the availability of any applicable items and services to Medicare beneficiaries without the authorization of CMS, and only then in accordance with CMS-issued guidance.
    b. In submitting bids, PBPs, formularies and other similar annual benefit-related items to CMS for Calendar Year 2017, applicant shall:

i. Comply with any supplemental instructions issued by CMS for applicants to the Enhanced MTM model test;

ii. Include any associated changes in Part D drug costs expected due to Enhanced MTM model participation in the Part D bid (BPT);

iii. Prepare and submit an updated Enhanced MTM (administrative) cost proposal consistent with the actuarial and financial documentation submitted with the 2017 Part D bid, as directed by CMS;

iv. Not structure the benefit package, formulary or other feature of any plan so as to discriminate against any Medicare beneficiary.

6. <<name of user>> is a representative, officer, chief executive officer, or general partner of the business organization that is applying to participate in this model test, authorized to submit this application on applicant's behalf.

[signature box] I agree to the above on behalf of the applicant PDP sponsors.