

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop WB-06-05
Baltimore, Maryland 21244-1850



CENTER FOR MEDICARE & MEDICAID INNOVATION

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TO: All Prescription Drug Plan (PDP) Sponsors

FROM: Sheila Hanley
Director, Policy and Programs Group
Center for Medicare & Medicaid Innovation

SUBJECT: Announcement of Part D Enhanced Medication Therapy Management Model Test

This memorandum announces the Part D Enhanced Medication Therapy Management (MTM) Model, and provides preliminary information to sponsors of stand-alone individual market basic PDPs interested in participation. CMS is conducting this model test through the Center for Medicare and Medicaid Innovation under Section 1115A of the Social Security Act.

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. CMS anticipates the model will begin on January 1, 2017. The proposed duration of the initial model test performance period is five years, from CY 2017 through CY 2021. The full duration of the model test will span 7 years, as CMMI will continue to make performance-based payments for two additional years after the model performance period.

CMS intends to 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). Organizations interested in participating are strongly encouraged to begin designing programs and preparing proposals in accordance with the guidance below, in advance of the formal Request for Applications. However, the parameters of the Part D Enhanced MTM Model described in this Announcement may change, or CMS may ultimately decline to conduct the model test, at CMS's sole discretion.

CMS welcomes feedback and reactions to this Announcement from all interested parties. Instructions for supplying this feedback are found at the end of this Announcement.

Background

Medication Therapy Management (MTM) is a term that 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 Part D 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 minimal compliance standards. Current Part D MTM regulations require uniform service offerings to beneficiaries who meet the plan's MTM 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.

Section 3021 of the Affordable Care Act (codified at Section 1115A of the Social Security Act) established the Innovation Center for the purpose of testing "innovative payment and service delivery models to reduce program expenditures ... while preserving or enhancing the quality of care" for individuals covered by Medicare, Medicaid, or the Children's Health Insurance Program. CMS intends to implement a model test with five performance years under this authority that 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.

Key elements of this model would 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; and
- 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.

If successful, this model will result in stand-alone individual market basic 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 primary research question this model is testing is: What is the impact of granting stand-alone PDP sponsors a limited waiver of existing uniformity and related requirements and providing financial incentives outside of the bid to test innovative MTM interventions? More granular questions include: What is the impact on patient outcomes and satisfaction? What is the impact on plan expenditures and on Medicare expenditures? What are the market-level impacts? Are a substantial proportion of beneficiaries being touched by model interventions? What are the effects on plan bids?

The Model Design

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.

A. Geographic Scope

CMMI has selected specific regions in which to test this model. 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. The model will be tested in 5 of the 34 existing (U.S.) 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)

This set of regions was selected so as to allow for a sufficiently powered model test with comparison regions and to (in aggregate) be broadly representative of national market characteristics.

All plans within the test regions that meet certain minimum criteria (specified in Key Proposal Requirements Section A, “Eligible Plans”, below) will be eligible to participate on a voluntary basis. However, a sponsor who chooses to participate in the model test will be required to participate in all test regions in which a qualifying plan is offered.

B. Relation to Part D MTM Program

The components of this model will differ from and replace the current Part D program MTM requirements. Participating sponsors will not submit their standard MTM programs for approval to CMS or include these utilization and cost assumptions in their Part D plan bids. Instead, the sponsor will

submit detailed descriptions of alternative Enhanced MTM program eligibility targeting criteria and interventions to CMMI 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 interventions outside the Part D bid. All Part D drug costs remain in the Part D bid.

C. Enhanced and Individualized MTM Strategies

The model features a combination of regulatory flexibilities and payment reform incentives. The regulatory flexibilities will permit participating stand-alone basic PDP sponsors to risk stratify the population enrolled in their basic plans 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 enrollees 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 PDPs to support the cost of the expansion interventions, and (2) a performance payment to plans that are successful in improving outcomes and reducing Part 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 (as opposed to drug costs) in their bids. The second incentive will take the form of a premium subsidy in a future year; therefore, 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 could vary the intensity and types of services based on beneficiary risk level, as well as provide beneficiary incentives to ensure participation. Participating PDPs could offer higher-risk beneficiaries—those at higher clinical risk, and those most likely to opt out of the MTM program—with higher-touch services, such as more frequent person-to-person consultations, now offered annually, or CMRs after transitions of care or other changes in risk status. In contrast to the current one-time CMR approach, this may allow counselors to assess both medication use and the beneficiary’s understanding on an on-going basis, and to follow up with additional interventions when necessary for the beneficiary and/or prescriber. PDPs could offer lower-risk beneficiaries lower-touch services. PDPs could assess the need to offer an annual CMR consultation based on individual beneficiary needs.

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. CMS stakeholder outreach has suggested significant consensus around the value of the following strategies:

- 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 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 emergency department (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 prescribed drug class to reduce cost sharing barriers for financially needy enrollees;
- Copay assistance when required to eliminate financial barriers 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 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
- Other beneficiary incentives when necessary to incent meaningful care management program participation and behavior change.

D. Waivers

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.

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). For this model and consistent with this standard, the Secretary may consider issuing waivers of certain fraud and abuse provisions in Sections 1128A, 1128B, and 1877 of the Act. In support of the model intervention, the Secretary intends to waive certain Title XVIII statutes and their implementing rules, to the extent described below.

No waivers of any kind are being issued in this document, which merely describes the 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 Announcement, 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.

MTM Requirements [SSA § 1860D-4(c)(2); 42 CFR 423.153(d)]—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 required interventions under Section 1860D-4(c)(2)(C) and 42 CFR 423.153(d)(1)(v – vii) , all in accordance with the 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 [SSA § 1860D–2(a); 42 CFR 423.104(b)(2)]—To the extent a permitted intervention is considered an additional benefit, and not an element of an MTM program, waived to permit stand-alone basic PDP sponsors to offer supplemental items and services to the clinically-targeted enrollee population, rather than the entire plan membership.

Uniform Cost Sharing [SSA § 1860D–2(a); 42 CFR 423.104(b)(2)]—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 [SSA § 1860D-2(b)(4)(C)(ii); 42 CFR 423.100]—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”.¹ This treatment will prevent such amounts from being counted toward plan payments (through Part D reconciliation) while also ensuring that there is no disincentive to either beneficiaries or plan sponsors due to changes in application toward the TrOOP threshold.

Disclosure [SSA § 1860D-4(a)(1); 42 CFR § 423.128]—Waived to the extent necessary for a 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 [SSA § 1860D-13, 15; 42 USC § 1395w-113, 115]—Waived to the extent necessary to permit payments for the MTM services as provided under the model, and not as specified under the waived provisions.

Minimum Loss Ratio Reporting [SSA § 1860D-12(b)(3)(D); 42 CFR § 423.2430]—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.

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

Waivers are contingent on compliance with the terms and conditions of the model, and are granted only to the extent necessary to implement a participant’s approved programmatic proposal. CMS reserves the right to revoke the waivers or suspend model testing at any point.

E. New Prospective Payment

¹ For purposes of reporting reductions in cost sharing under this model only, CMS will instruct participating model plans to include waived amounts in the Other TrOOP field on Prescription Drug Events (PDEs).

As part of this model, CMS will offer participating plans a new per-member-per-month (PMPM) prospective payment to provide funding for enhanced benefits and services, as well as pharmacy or beneficiary incentives, and resources to support interoperable data exchanges on MTM services, including potentially with prescribers. Thus, we will fund the costs of the new risk-stratified and patient-targeted interventions outside of the bid, in order to eliminate the competitive disincentive plans currently have to invest in these interventions. Plan sponsors will have the flexibility to differentially target beneficiaries and invest in interventions. Our expectation is that the actual cost will vary by plan, based on the specific interventions proposed.

As described further below, sponsors will be 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. 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 spread across the entire projected plan enrollment. Thus, the approved PMPM amounts will be paid per enrollee in the plan regardless of how many of those enrollees are receiving the enhanced MTM items or services. CMS will not adjust these prospective payment amounts for actual expenditures, but will permit annual updates, and will require at least annual actual cost reporting. The Enhanced MTM PMPM would be submitted for approval and paid in each performance year of the model and could change on an annual basis.

The costs funded by these prospective payments will be treated as quality improving activities for purposes of Part D MLR reporting requirements. This is consistent with the regulatory intent of including the costs related to quality-improving activities in the numerator of the ratio because they are expected to result in improved quality outcomes and lead to a healthier beneficiary population. In particular, activities that can be billed or allocated by a pharmacy for care delivery and that are reimbursed as clinical services may be treated as quality improving activities.

F. New Performance-Based Payment

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 amount, which is equal to the level of recent LIS 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 be receiving 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-premium-subsidy calculations. In other words, the premium reduction will be considered in determining the low-income premium benchmark. This lower beneficiary premium will make the plan more competitive relative to both its competitors and the low-income premium

benchmark amount. Thus, while enrollees will be the direct beneficiaries of this performance payment, plans will also have a strong motivation to earn this extra subsidy.

Performance results in model Year One (2017) will translate into a performance-based payment in Year 3 (2019). This timing would be similar to the lag in the effect of the Part C&D Star Ratings on Medicare Advantage (MA) quality bonus payments. Similarly, performance results from model Year Two (2018) would determine the payment in model Year Four (2020), and performance results from model Year Three (2019) would determine the payment in model Year Five (2021). If earned in model Years Four and Five, the performance 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 cost 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. Note that this approach of offsetting Parts A and B cost savings by the aggregate amount of prospective payments for the same period offers plans a strong encouragement to be judicious when determining the upfront cost of their intervention, since this amount will count against them when calculating savings for purposes of determining eligibility for performance payments. CMS is setting a minimum savings rate of 2%, in order to qualify for the performance payment. This level is consistent with our general expectations about the magnitude of the potential impact of this model, and is also sufficiently large that the risk of paying performance payments based on random variations in expenditures is limited.

In order to calculate savings, participating plans' Medicare expenditures in the intervention year will be compared to a performance-payment benchmark, which will be determined based on expected Medicare costs. To calculate the performance-payment benchmark, CMS proposes 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 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. Precise parameters for calculating the benchmark will be determined with the assistance of a technical and an evaluation contractor, and will be shared with participating plans prior to their signing a final participation agreement. In addition to meeting savings requirements, plans must satisfactorily report all required model data elements in order to qualify for the performance payment. See the following section for more details. 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.

G. 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.

The uniform set of data elements to be collected will include data on specific beneficiary-level interventions and outcomes. These will be identified through the use of Systematized Nomenclature of Medicine (SNOMED) codes whenever practicable. SNOMED 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 automatic interpretation of these.

Examples of SNOMED intervention codes include:

Intervention	SNOMED code
Medication reminder device set-up	435441000124107
Medication equipment or device education	362978005
Chronic Disease education	423167009
Change length of therapy	Code pending

Examples of SNOMED outcomes codes include:

Outcomes	SNOMED code
Patient condition resolved	370996005
Patient cured	371001000
Patient condition improved	268910001
Patient condition poor	162667001

More specifically, CMS intends to collect MTM encounter data incorporating elements such as dates, provider identifiers, and coupled SNOMED codes whenever possible in order 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 the 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.

Key principles in developing quality indicators will include (1) clinical significance, and (2) a clear link to improved outcomes. CMS will engage a contractor to develop detailed data collection and validation specifications by mid-2016. Data and measurement selection will require consultation with internal quality subject matter experts and external MTM quality stakeholders, extensive up-front work developing definitions and specifications, and ongoing work conducting data validation and analysis. Potential quality indicators may include (but are not limited to) the following metrics under consideration by the Pharmacy Quality Alliance (PQA) and the Joint Commission of Pharmacy Practitioners (JCPP):

Metric	Potential Definition
1. Percentage of patients who had medication reconciliation after a transition of care.	[PQA] The percentage of high-risk patients that have been discharged from the hospital and that receive MTM from a pharmacist within 7 days
2. Percentage of patients who had MTM services post discharge and were readmitted to hospital within 30 days.	[PQA] The percentage of high-risk patients that received MTM from a pharmacist within 7 days post hospital discharge that are readmitted within 30 days of their discharge.
3. The percentage of prescriptions e-prescribed by a prescriber and not obtained by the patient in the following 30 days	[PQA] The percentage of prescriptions for chronic medications e-prescribed by a prescriber and not obtained by the patient in the following 30 days.
4. The percentage of clinically significant drug events resolved.	[JCPP] The total number of drug therapy problems identified (denominator) versus the total number of drug therapy problems resolved (clinical goal achieved) (numerator) as a %.
5. The prescriber goals of therapy achieved at follow-up visits versus initial visit.	[JCPP] % of patient conditions at goal of therapy at baseline visit versus % of patient conditions at goal of therapy on subsequent (latest visit) visit related to DTP recognized and resolved.
6. Proportion of targeted beneficiaries for whom the Plan sponsor provided medication history to EHR.	# of patients where the PDP shares medication data to physician via the electronic health record.
7. Cost (prospective payment) per clinically significant intervention.	The cost of each intervention versus the total prospective payment.

In addition to the uniform set of data, CMS also expects each plan sponsor to identify and propose its own metrics for its own internal protocols and learning systems. The Plan sponsor metrics and associated data elements will vary based on plan sponsor and the MTM intervention proposed by the sponsor. The model team will use both the uniform and plan-sponsor-specific indicators as a means to monitor compliance with the test program and, over time, as a means to look at whether the plan interventions are correlated with outcomes such as mortality, ER utilization, or hospital readmissions, or beneficiary satisfaction measures.

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 opportunity to comment and provide feedback before any decisions on these topics are finalized.

H. Strengthened Linkages with Prescribers and Pharmacists

Stand-alone basic PDP sponsors currently have online real-time telecommunication linkages with network pharmacies, primarily for claims adjudication and payment, and other web-enabled linkages with other MTM vendors. However, sponsors may lack information to help assess medication-related risks, such as claims or other descriptors of ongoing medical care or alignment of beneficiaries with an

ACO. Without more information and improved linkages, PDP sponsor interactions with prescribers are more likely to be limited (e.g., unsolicited fax alerts to prescribers to request substitution of formulary alternatives or to report apparent gaps in refills that may not be accurate) and less than fully effective.

The Part D Enhanced MTM Model is intended to incentivize strengthened linkages among sponsors, pharmacies, and prescribers. Incentives will be aligned to detect and prevent medication-related risks. In particular, this model will 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 use, 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.

I. CMS Provision of Medical Data to Sponsors

To support the strengthened linkages described above, CMS intends to modify existing systems to provide model participating sponsors with beneficiary Medicare Parts A&B claims data, upon request, to enable participating sponsors to see the services an enrollee has received and to provide greater context for each participating beneficiary's medication regimen. To assist participating sponsors in creating improved linkages with integrated care management teams, CMS may also provide access to information regarding beneficiary alignment with integrated care models, such as the ACO alignment records managed in CMS's Master Data Management (MDM) system.

This Medicare Parts A and B data would be made available to participating Part D sponsors for purposes of their health care operations involving quality improvement and/or care coordination and the data would be limited to the sponsors' enrollees. To receive access to this 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 activities, 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.

Key Proposal Requirements

A. Eligible Plans

In order to participate in this model, a plan must (a) be an individual market stand-alone basic plan, (b) have a minimum enrollment of 2,000, (c) have existed as a basic plan for at least three years prior to first year of the model test, and (d) 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 auto-assignees and lack of full 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 power for meaningful statistical evaluation of changes in predicted outcomes to be reliably measured. The three-year history (prior to first year of the model test, i.e., 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 these minimum 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 – see below.) A sponsor who chooses to participate in the model test must participate in all test regions in which a qualifying plan is offered each year. A plan sponsor may exit the model after the completion of any one year, but none may join after the first year.

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 Part D quality strategy and support its efforts to improve its quality performance. 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. 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 plans submitting an initial application for participation in the model, and plans that see their quality scores drop during the course of model implementation. 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.

B. Target Population & Eligible Beneficiaries

Plan sponsors will not be required to limit interventions to pre-defined beneficiary categories, but will be required to submit written plans for their proposed protocols outlining how they will target beneficiaries. Our expectation is that 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 health care services;
- Lack of social supports; and

- 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). We expect 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 would be submitted through MARx to the Medicare Beneficiary Database (MBD) or other specific CMS beneficiary data system of record where it would be stored.

C. Plan Marketing and Enrollee 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 are not permitted to mention the plan’s participation in the model to beneficiaries who are 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 specifically inquires about them. Such discussions must be accompanied by a disclaimer indicating that eligibility for interventions is not assured, and will be determined by the 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 other public-facing documents or sites, as appropriate, wherever MTM-specific disclosures are required.

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. Since model interventions are (by design) highly individualized, we do not believe such notices will typically be standardized or contain CMS-approved model language. A model objective is to encourage innovation in targeting and beneficiary engagement around medication-related risk, and any attempt to direct or standardize materials would be inconsistent with that objective. 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 in many cases these will be more effective than call-center or mail contacts from the PDP.

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 that these be submitted for review by the model team prior to use to ensure, among other things, that they are not misleading or confusing.

D. Beneficiary Protections

Multiple protections for beneficiaries are built into the design of this model. Most importantly, plans may not under any circumstances increase cost sharing or reduce benefits for either targeted or non-targeted enrollees. CMS will review plans' proposed interventions for clinical plausibility and to ensure that they are not discriminatory.

In addition, CMS intends to layer several additional beneficiary protections on top of those embedded in plan design. These include:

- Development of standardized high-level model language for disclosure of the plan's participation in this model in the Evidence of Coverage, the Medicare Plan Finder, and other public-facing documents or sites wherever MTM-specific disclosures are required;
- Construction of a customized script for any calls to plan sponsors, 1-800-MEDICARE customer service representatives, and CMS contractors related to the Enhanced MTM model, and standardized process for following-up on any beneficiary complaints;
- Standardized process for receiving and reviewing any provider complaints related to the model;
- Ongoing monitoring of incoming plan data, to ensure that there is no evidence of significant deterioration in patient outcomes or satisfaction; and
- Ongoing monitoring of incoming plan data, to ensure there is no significant difference in Part D pricing compared to other sponsor plans that might be associated with plan participation in this model.

CMS reserves the right to terminate a plan's participation in the model at any time if there is evidence to suggest that the plan's participation in the model is jeopardizing the integrity of the model or resulting in lower quality care or any other adverse outcomes for beneficiaries.

E. Learning Systems

CMS will provide sponsors participating in this model with learning activities and resources, intended to provide background and technical support, share best practices, and accelerate model implementation and results. As part of these learning activities participating plans will be expected to share their experiences and/or lessons learned from their participation in the model. (Any such requirements will be developed in light of the need to protect proprietary information in a competitive market-based program.)

Participating sponsors will also be required to develop internal (sponsor-specific) learning systems, which will allow for collection, evaluation, and dissemination about sponsor or plan-specific lessons learned on interventions to beneficiaries, prescribers, pharmacists and other stakeholders. Plans will be expected to describe their proposed learning systems before the start of the model performance period, and participate in periodic individual conferences calls with CMS to provide updates.

F. Other Rules and Restrictions

Sources of Funding—The only sources of funding that may be used under the model will be the new prospective payments, or negligible administrative funds from the sponsor’s Part D operating margin. 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 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 and other model participants 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 assure non-brand or manufacturer-specific related criteria are used.
- Stand-alone basic PDP sponsors are permitted to 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 change to a beneficiary’s drug regimen (other than generic substitutions) only when doing so is in the beneficiary’s interest.

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 by providing additional items and services directly to beneficiaries as appropriate. We expect 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 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, we will require that stand-alone basic PDP sponsors’ intervention plans must 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 medication therapy management and other related health care purposes, or if other potential uses are incidental.
- Stand-alone basic the PDP sponsor may not market the MTM program. The program must be explained in direct communications to MTM-enrolled beneficiaries.

MTM Services Delivered through Pharmacies—Stand-alone basic PDP sponsors and subcontracted MTM vendors may seek to engage pharmacies in the MTM process, and may further subcontract certain duties or contract with them to engage in the MTM process. We recognize that pharmacies may be owned by or affiliated with a stand-alone basic PDP sponsor or PBM. Pharmacies might be compensated by the 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.

Risks inherent in these enhanced arrangements include payments to the pharmacy might be masked payments to steer beneficiaries to the stand-alone basic PDP, or that a pharmacy might recommend and provide home delivery or compliance packaging when not clinically indicated for the beneficiary, in order to provide the service at a profit or to encourage the retention of beneficiaries as customers. To address this risk, CMS will require that contracted items and services, and the protocols and criteria for the dispensing of items and services, must 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. We would expect the stand-alone basic PDP sponsor to establish protocols for pharmacy delivery of items or services and to monitor the pharmacies' compliance and appropriateness of use.

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 would not be permitted.

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

reduction of copayments (Part D), other copay assistance to promote needed medical assessment and/or follow-up (Part B, e.g., for lab tests), or other incentives for protocol compliance as determined on an individual basis. 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. To address these risks, CMS will require at least the following:

- Stand-alone basic PDP sponsors must specify the protocol or criteria they will apply before offering the incentives, and the criteria they will apply for withdrawing the incentives.
- 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 stand-alone basic 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.

Participant Application, Selection and Contracting

CMS will solicit model participants via a Request for Applications. Model participant selection is not competitive. CMS will admit all interested stand-alone individual market basic PDP sponsors that timely apply to the model test, provided the stand-alone PDP sponsor and its proposed basic plan meet CMS's participation criteria, and the stand-alone basic PDP sponsor's programmatic proposal is acceptable to CMS. CMS will reserve the right to disallow participation to preserve the welfare of beneficiaries or other related grounds.

A. Applications

Interested organizations must apply to participate by response to a Request for Applications ("RFA"). CMS intends to release the RFA in the fall of 2015 through the Health Plan Management System. Applications will be submitted to CMS electronically around the end of 2015 or beginning of 2016 at a date and time to be specified by CMS, and specific Enhanced MTM model contacts will be identified by the eligible stand-alone basic PDP sponsors. 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.

Organizations must respond to the RFA with sufficient specificity for CMS to evaluate and understand their proposal in detail. Once contracted to participate in the model, each organization will be bound to adhere to its response to the RFA and to fully implement its proposal. Modifications will be permitted only with express approval of CMS.

Organizations will be 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. Participation is voluntary; however, a sponsor that chooses to participate in the model test shall participate in all test regions in which a qualifying plan is offered.

The RFA will require that interested sponsors respond in a narrative format, describing their MTM intervention plans in detail, e.g., the new eligibility 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. 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. The actuarial estimates will be reviewed by the model team (and actuarial services contractor) to identify any significant concerns that warrant additional scrutiny and/or revision. CMS will also require approved participants to submit updates to their plans on an as-needed basis.

As part of the application, applicants will (at a minimum) 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 costs; in other words, the mechanism by which it expects outcomes will be affected, the goals it will set, and how it will measure progress towards goals;
- An outline of all payment flows incorporated in the plan's implementation plan;
- A projection of the PMPM cost of the plan's proposed interventions certified by a Member of the American Academy of Actuaries; and
- If applicable, a narrative description of the process and criteria for assessing and applying cost sharing assistance to financially needy enrollees.

In both the narrative and cost assumptions of the application, we would expect to see variations on the intervention strategies outlined above, 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 would not be considered sufficient to significantly increase enrollment. We would expect to see protocols involving multi-pronged, proactive, and persistent efforts to make contact with 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. Indeed, a satisfactory review of the assumptions behind the engagement rates will be central to CMS approval of a plan's proposal.

In general, CMS will review applicants' proposed interventions and justifications to ensure that they meet a minimum threshold of clinical plausibility, are consistent with the utilization assumptions in the

actuarial estimates, and that they are not likely to lead to adverse or unintended consequences. Proposed interventions that fail to meet this standard will not be approved. As noted above, the application process will not be competitive; rather all qualified applicants within a geographic region will be accepted. Given this, there would be room for CMS to negotiate with applicants if their application proved inadequate in some way, rather than simply rejecting it.

CMS will also require all applicants to disclose any present or past history of sanctions, investigations, probations or corrective action plans for the applicant or other related persons and entities. CMS will conduct appropriate program integrity screens during the application process, and reserves the right not to select otherwise qualified applicants on the basis of information found during a program integrity screen.

B. Selection

Participation in the Part D Enhanced MTM Model is not competitive. CMS will accept existing Part D sponsors supplying acceptable proposals that meet the model's participation criteria. All plans within the test regions that meet the model's participation criteria will be eligible to participate on a voluntary basis subject to the requirement that a sponsor who chooses to participate in the model test shall participate in all test regions in which a qualifying plan is offered.

In addition to the criteria already stated, CMS will reserve 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.

The participant selection requirements are in addition to any participation requirements generally applicable to the Medicare Part D program. A condition of continuing participation in the Part D Enhanced MTM Model is that the enrolled plan continues to be offered and open for enrollment in the Part D program.

C. 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 that have been provided to the plan at the time the addendum is signed and incorporated by reference. CMS expects to enter into final addenda in September 2016 concurrently with the signing of other Part D contract documents.

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. 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 aggregate value of model prospective payments in that year.

Further, an organization's failure to adhere to the requirements of the model test may result in rescission or invalidation of a waiver issued to that organization, which could trigger enforcement action 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.

Participating stand-alone basic PDP sponsors will execute Part D contract addendum agreements that will include terms and conditions which 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 drugs or 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; and
- Requirement for retrospective reporting on actual costs of model.

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.

Model Timeline

Date	Milestone
October 2015	Request for Application (RFA) Released
January 2016	Model Applications Due to CMS
March 2016	Provisionally Selected Model Plan Participants Identified
July 2016	Potential 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

Model Design Feedback

CMS welcomes feedback on this Announcement from all interested parties. Please direct responses to EnhancedMTM@cms.hhs.gov. To receive full consideration, correspondence should identify the sender and the organization represented. This email box is intended for model design feedback.

Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this Announcement; all costs associated with responding to this Announcement will be solely at the interested party's expense. There is no requirement to respond to this Announcement. Not responding to this Announcement does not preclude participation in the Part D Enhanced MTM Model or any future procurement, if conducted. It is the responsibility of the potential responders to monitor for additional information pertaining to the Part D Enhanced MTM Model.

Please note that CMS will not respond to questions about the policy issues raised in this Announcement. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written submissions by interested parties. Contractor support personnel may be used to review responses. Responses to this notice are not offers and cannot be accepted by the Government to form a binding contract or issue a grant. Information obtained as a result of this Announcement may be used by the Government for program planning. Respondents should not include any information that might be considered proprietary or confidential. All submissions become Government property and will not be returned. CMS may publically post the comments received, or a summary thereof.

This is an Announcement only. This Announcement is issued solely for information and planning purposes; it does not constitute a Request for Proposal, applications, proposal abstracts, or quotations. This Announcement does not commit the Government to contract for any supplies or services or make a grant award. This Announcement should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. Further, CMS is not seeking proposals through this Announcement and will not accept unsolicited proposals.