Centers for Medicare & Medicaid Services
Center for Medicare and Medicaid Innovation

Part D Payment Modernization Model
Request for Applications for CY 2021

Table of Contents

1. Background and General Information

The Centers for Medicare & Medicaid Services (CMS) is seeking applications from eligible Prescription Drug Plans (PDPs) and Medicare Advantage Organizations offering Medicare Advantage- Prescription Drug Plans (MA-PDs) collectively ("Part D sponsors") to participate in the Part D Payment Modernization Model (PDM Model or "the Model") for Contract Year ("CY"') 2021. This request for applications (RFA) outlines Model design elements, Model eligibility criteria, and additional Model details for organizations interested in applying for CY 2021. All eligible organizations that wish to participate in the PDM Model for CY 2021, including organizations that are participating in CY 2020, must apply for participation in the Model.

The Part D Payment Modernization Model RFA is open to eligible organizations nationally. Eligible Part D sponsors applying with one or more stand-alone PDP(s) in a region must include all of their stand-alone PDP plan benefit packages (PBPs) in that Part D region. Eligible MA Organizations applying with one or more MA-PD PBP(s) must identify the PDP region or regions that the PBP(s) are offered in and must include all MA-PD plans with service areas that include those PDP region(s). Except as described in the next paragraph, Part D sponsors (offering PDPs or MA-PDs), including those that offer standard or alternative Part D coverage (defined standard, actuarially equivalent standard, basic alternative, and enhanced alternative plans), are eligible to apply to participate in the PDM Model. In addition, for CY 2021, all types of Special Needs Plans (SNPs) are eligible to apply to participate in the Model.

The following plan types are not eligible for participation in the Model: Private fee-for-service plans, employer/union only direct contract plans (local coordinated care plans, prescription drug plans, private fee-for-service plans), section 1876 cost contract plans, section 1833 health care prepayment plans, Programs of All-Inclusive Care for the Elderly (PACE), Medicare-Medicaid plans, and religious fraternal benefit plans (local coordinated care plans and private fee-for-service plans).

In the event a PBP is in both the Part D Senior Savings Model and in the Part D Payment Modernization Model, during settlement, if a PBP would receive performance-based savings, CMS will apply a standard adjustment factor to account for federal reinsurance savings second to participating in both Models, as deemed necessary by CMS. The adjustment would not move a participating PBP from performance-based savings to performance-based losses but is intended to adjust for savings secondary to overlap between the two models.

For CY 2021, the PDM Model has been updated to allow CMS to test additional programmatic flexibilities summarized below and described in detail throughout this RFA. CMS is conducting this Model test through the Center for Medicare and Medicaid Innovation's authority provided under Section 1115A of the Social Security Act.

1.1 Model Scope and General Approach

The PDM Model began on January 1, 2020. The Model will be tested for five performance years, ending on December 31, 2024. In order to address the high list price and high beneficiary out-of-pocket costs of prescription drugs, CMS is testing the impact of an updated Medicare Part D payment structure focused on the catastrophic phase of the Part D benefit. Through testing a change to the Part D payment structure and providing additional programmatic flexibilities, the Model tests how modernizing the Part D payment structure can incentivize plans to specifically help lower federal reinsurance subsidy spending, in addition to overall Part D spending and beneficiary out-of-pocket costs.

The voluntary, five-year Model modernizes the Part D payment structure through increasing Part D sponsor liability in the catastrophic phase of Part D to address rising federal reinsurance subsidy spending. Part D Sponsors that are approved to participate in the Model will take two-sided risk for CMS's federal reinsurance subsidy (80 percent of catastrophic phase liability) for all eligible PDPs or MA-PDs that they offer, allowing for performance-based payments from, or additional payments to, CMS based on spending.

By balancing plan sponsors' additional catastrophic phase risk in a competitive Part D market with the potential earning of performance-based payments, the Model will test how participating plan sponsors can maintain and enhance accessibility and affordability of covered Part D drugs for their enrollees, while better managing overall spending. Through the Model, CMS will understand the impact of better aligning risk, incentives, and additional specific program flexibilities on costs for beneficiaries and the Medicare program as well as how the delivery of clinical prescription drug management services can impact the adherence and appropriateness of Part D medication regimens and any subsequent long-term decreases in Parts A and B spending.

1.2 Summary of Model Programmatic Flexibilities for Contract Year (CY) 2021

For CY 2021, Model participants may apply to CMS to offer the following range of programmatic flexibilities and model design elements:

a. Medication Therapy Management+ (MTM+) Program (new for 2021);
b. New Flexibilities to Lower Costs for Beneficiaries: Limited initial days' supply and Cost-Sharing Smoothing (new for 2021);
c. Part D Rewards and Incentives Programs;
d. Reduction or Elimination of Cost-Sharing on Generic Drugs and Biosimilars for Low-Income Subsidy Beneficiaries (allowed for basic and enhanced alternative plan types);
e. Additional Flexibility under the De Minimis Policy; and
f. Plan Timeliness for Standard Initial Coverage Determinations.

Each of these programmatic flexibilities for CY 2021 is discussed in more detail in section 2.2 below.

1.3 Statutory Authority

Section 1115A of the Social Security Act (the Act) (42 U.S.C. § 1315a, added by Section 3021 of the Patient Protection and Affordable Care Act) authorizes CMS to test innovative healthcare payment and service delivery models that have the potential to lower Medicare, Medicaid, and Children's Health Insurance Program (CHIP) spending while maintaining or improving the quality of beneficiaries' care.

1.4 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). For this Model and consistent with this standard, the Secretary may issue waivers of certain fraud and abuse provisions in sections 1128A, 1128B, and 1877 of the Act.

1.5 Medicare Program and Payment Waivers

In support of the PDM Model, the Secretary intends to waive certain requirements under Title XVIII of the Social Security Act and its implementing regulations for purposes of testing this Model. No waivers of any kind are being issued in this document, which merely describes certain waivers contemplated at this time for the PDM Model in CY 2021. Programmatic waivers under consideration for CY 2021 are the following:

- **Additional Payments to Plan Sponsors:** Section 1860D-15(a) of the Social Security Act and 42 C.F.R. Section 423.329(a), to the extent necessary to allow CMS to make additional payments, including but not limited to performance-based payments, to Part D sponsors participating in the Model.
- **MTM Requirements:** Section 1860D–4(c)(2) of the Act (42 U.S.C. 1395w-104) and the regulatory provision at 42 C.F.R. 423.153(d) to the extent necessary to permit Part D 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 C.F.R. 423.153(d)(2)), and to offer those enrollees an MTM+ program that does not contain the minimum elements and interventions under Section 1860D-4(c)(2)(C) and 42 C.F.R. 423.153(d)(1)(iii, v – vii), all in accordance with the Part D sponsor's approved proposal.
- **Part D Catastrophic Phase Liability Distribution:** Section 1860D-15(b) of the Social Security Act and 42 C.F.R. Section 423.329(c), to the extent necessary to allow Part D sponsors to take two-sided risk on the federal reinsurance subsidy and modifying the method for calculating reinsurance payments.
- **Part D Bid and Payment Data:** Section 1860D-15(f) to the extent necessary to permit CMS to use Part D bid and payment data for purposes of conducting and evaluating the Model.

- **Plan Timeliness for Standard Initial Coverage Determinations:** 42 C.F.R. § 423.568(b) to the extent necessary to permit Part D sponsors to increase the standard coverage determination timeframe from 72 to 96 hours for requests for drug coverage.

- **Reduction or Elimination of Cost-Sharing on Generic Drugs and Biosimilars for Low-Income Subsidy Beneficiaries:** Section 1860D-14(a)(1)(D) of the Act) and 42 C.F.R. Part 423, Subpart P to the extent necessary to allow Part D sponsors to reduce or eliminate cost-sharing on generic drugs and biosimilar for low-income subsidy beneficiaries, subject to the terms of the Model.

- **Uniformity and Accessibility of Benefits:** Section 1860D–2(a) of the Act and 42 C.F.R. Section 423.104(b)(2) to the extent necessary to establish that a permitted intervention is considered an element of an MTM+ program, rather than an additional benefit and to permit Part D sponsors to offer supplemental items and services to the clinically targeted enrollee population, rather than the entire plan membership, consistent with the terms of Model.

- **Uniform Cost-Sharing:** Section 1860D–2(a) of the Act and 42 C.F.R. Section 423.104(b)(2) to the extent necessary to permit Part D sponsors to offer reductions in cost-sharing consistent with the terms of the Model, including to the enrollees targeted by the MTM+ program, but not to the entire plan membership.

- **Stars Ratings for Part D Plans:** 42 C.F.R. § 423.186 to the extent necessary to mitigate any statistically significant impacts to the Part C or D Star Ratings that are directly attributable to the PDM Model.

Program waivers, once issued, are (1) each contingent on compliance with the terms and conditions of the Model, including the contractual addendum for participation in the Model and documents incorporated therein; (2) are granted only to the extent necessary to implement an organization's approved proposal for participation; and (3) are granted only for the term of the addendum for participation in the Model. CMS reserves the right to revoke one or more of the Title XVIII waivers or to suspend model testing (or both) at any point. Further, all other (i.e., non-waived) requirements will continue to apply and be enforced.

1.6 Fraud and Abuse Waivers

As noted above, for this Model and consistent with the standard set forth in Section 1115A(d)(1), the Secretary may issue waivers of certain fraud and abuse provisions in Sections 1128A, 1128B, and 1877 of the Act. Fraud or abuse waivers are not being issued in this document; fraud and abuse waivers for the Model have been set forth in separately issued documentation, as may be amended from time to time (e.g., to reflect programmatic changes). Thus, notwithstanding any other provisions of this RFA, all individuals and entities must comply with all applicable laws and regulations, except as explicitly provided in such separately documented waiver issued pursuant to Section 1115A(d)(1) specifically for the PDM Model. Such waivers apply solely to the PDM Model and differ in scope or design from waivers granted for other programs or models.

2. Description of Model

2.1 Purpose and Concept

U.S. prescription drug spending and patient out-of-pocket costs continue to be a core topic of public discussion and policy interest. While prescription drugs for high prevalence chronic conditions in the U.S., such as cardiovascular disease, predominated Part D utilization and spending in the benefit's early years, advances in research and development have allowed for cures and treatments with significantly different utilization patterns and costs. The economics of pricing for these and other drugs has also changed, with high list prices shifting spending for more Medicare beneficiaries into the catastrophic coverage phase of the Part D benefit. In the catastrophic coverage phase under the defined standard benefit, beneficiaries pay 5 percent, the plan pays 15 percent, and the government pays 80 percent of the costs after direct and indirect remuneration (DIR) through a fully reconciled, open-ended federal reinsurance subsidy.

Given advances in the biopharmaceutical industry, and the resultant costs and benefits of therapies that Medicare beneficiaries rely on, there is broad consensus among stakeholders that the catastrophic coverage phase of the Part D benefit should be modernized. One key policy theme is to modernize Part D by updating the Part D program's payment structure, which has been outlined in numerous reports, including the Administration's Blueprint to lower drug prices, the HHS Office of Inspector General's (OIG) report on high-price drugs, and MedPAC's June 2016 Report on *Improving Medicare Part D,* as well as MedPAC's March 2019 Report to Congress.[1,2,3,4] Through this Model, CMS is testing the impact of increased Part D sponsor liability in the catastrophic coverage phase on federal reinsurance subsidy spending.

2.2 Model Design Elements

The PDM Model tests the impact of re-designing the catastrophic coverage phase of the Part D benefit to increase Part D plan sponsor management of prescription drug prices and spending. If successful, this Model will decrease total Part D spending, including in the catastrophic phase, and improve beneficiary access to, and the affordability of, prescription drugs by targeting key drivers of increased Part D drug spending such as high list prices of new brand and specialty drug

[1] American Patients First. The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. May 2018. https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf
[2] Department of Health and Human Services Office of Inspector General. High-Price Drugs are Increasing Federal Payments for Medicare Part D Catastrophic Coverage. January 2017. https://oig.hhs.gov/oei/reports/oei-02-16-00270.pdf
[3] Medicare Payment Advisory Commission (MedPAC). Improving Medicare Part D. June 2016. http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf Scores, formulary and type of plan offering, and other factors as deemed appropriate by CMS. Historical and projected per capita federal reinsurance subsidy trends are available in the Medicare Trustees Report (Table IV.B9.–Incurred Reimbursement Amounts per Enrollee for Part D Expenditures).
[4] MedPAC March 2019 Report to Congress. http://www.medpac.gov/docs/default-source/reports/mar19_medpac_entirereport_sec.pdf?sfvrsn=0

therapies.

Payment Model Design Elements

Current Part D bid, payment, and reconciliation processes will continue to apply. The current 15 percent catastrophic coverage phase liability included in the direct subsidy will continue to be bid as part of the direct subsidy and reconciled as usual under current law. The 80 percent catastrophic phase liability currently bid as prospective federal reinsurance will continue to be bid as prospective federal reinsurance and reconciled as usual fully to actual spending. Finally, reconciled federal reinsurance subsidy spending will be assessed against a benchmark, as described below, to determine organization performance. The current 5 percent beneficiary liability in the catastrophic phase under the standard benefit will continue to apply.

As part of the Model test, following a plan year, CMS will calculate Spending Target Benchmark(s) for that plan year. All federal reinsurance subsidy spending for participating plan benefit packages (PBPs) will be aggregated by parent organization and product type to create spending target benchmarks – one that applies to the participant's stand-alone PDPs and one for its MA-PDs. The Spending Target Benchmark is the estimate of what plan federal reinsurance spending by stand-alone PDPs and MA-PDs in the parent organization would have been in the absence of the Model and will be developed using a multiple linear regression statistical modeling technique and calibrated based on the measurement cohort's performance year experience at a contract and plan benefit package level (PDP or MA-PD, as applicable).

Through Performance-Based Payments, CMS will share savings on federal reinsurance subsidy spending (Performance-Based Gains) relative to the Spending Target Benchmark with participating Part D sponsors. Through Performance-Based Recoveries, participating Part D sponsors will owe funds to CMS if federal reinsurance subsidy spending exceeds the Spending Target Benchmark (Performance-Based Losses). Specifically, if a Part D sponsor's spending is above the Spending Target Benchmark, the Part D sponsor pays ten percent of the difference between actual results and the benchmark. If the Part D sponsor's spending is below the Spending Target Benchmark, then it will receive 30 percent of the differential between the benchmark and actual spending and an additional 50 percent of marginal savings above three percent and actual spending.

Determinations of any payments from or due to CMS will be made once all available Part D Prescription Drug Event, direct and indirect remuneration, enrollment, and risk adjustment data are available and federal reinsurance subsidy reconciliation is finalized.

Part D sponsors may choose to elect a minimum threshold for Performance-Based Gains and Performance-Based Losses below which there would not be a Performance-Based Payment or Performance-Based Recovery. For CY 2021, that minimum threshold is an aggregate gain or

loss percentage of 0.5 percent, applied separately to stand-alone PDPs and MA-PDs. If a Part D sponsor elects to have the minimum threshold apply to its Spending Target Benchmark(s), the minimum threshold will apply to all of the Part D Sponsor's Model PBPs (i.e., PDP and MA-PD) and the Part D Sponsor will not share in any Performance-Based Gain or Performance-Based Loss, if the gain or loss percentage for that category of Model PBP is between minus (-) 0.5 percent or plus (+) 0.5 percent. Part D sponsors shall elect whether they are opting into the minimum threshold as part of the application.

Programmatic Model Design Elements

For CY 2021, the PDM Model will test the following six programmatic flexibilities:

a. Medication Therapy Management+ (MTM+) Programs;
b. New Flexibilities to Lower Costs for Beneficiaries: Limited Initial Days' Supply and Cost-Sharing Smoothing;
c. Part D Rewards and Incentives Programs;
d. Reduction or Elimination of Cost-Sharing on Generic Drugs and Biosimilars for Low-Income Subsidy Beneficiaries;
e. Plan Timeliness for Standard Initial Coverage Determinations; and
f. Additional Flexibility under the De Minimis Policy.

Each of these elements is described in detail below.

a. Medication Therapy Management+ (MTM+) Programs

Part D sponsors must include a CMS-approved MTM program as part of their Medicare Part D bid annually. CMS evaluates MTM programs to ensure that they meet the current minimum requirements for a program year in terms of targeting of enrollees. The general requirements outlined in 42 CFR 423.153(d) are that MTM programs target enrollees who meet all of the following: (i) have multiple chronic diseases, with three chronic diseases being the maximum, a Part D sponsor may require to qualify for targeting and two being the minimum; (ii) are taking multiple Part D drugs, with eight Part D drugs being the maximum number a Part D sponsor may require to qualify for targeting; and (iii) are likely to incur an annual Part D drug cost of $4,255 or more (for 2020). The regulation at 42 CFR 423.153(d) also outlines that the Part D sponsor must establish an MTM program that ensures covered Part D drugs are used to optimize therapeutic outcomes through improved medication use, reduces the risk of adverse events, is developed in cooperation with licensed and practicing pharmacies and physicians, and may be furnished by pharmacists or other qualified providers.

CMS data from 2019 on 649 total MTM programs showed that 73 percent of Part D Sponsors' contracts only target enrollees who meet the specified targeting criteria per CMS requirements, while 27 percent use expanded criteria. Specifically, 90 percent of 2019 programs targeted beneficiaries with at least three 3 chronic conditions, 78 percent of 2019 programs targeted beneficiaries who have filled at least 8 covered Part D drugs, and 79 percent of 2019 programs applied a methodology that projected annual drug costs based on covered Part D drug costs in the previous quarter. While incentives for stand-alone PDPs and MA-PDs should be different, since MA-PDs are responsible for medical costs in addition to prescription drug costs, MTM program design largely appears to be the same between stand-alone PDPs and MA-PDs, indicative of minimal innovation in MTM to date.

In January 2017, CMS began testing the Enhanced Medication Therapy Management Model (Enhanced MTM Model) for stand-alone basic Prescription Drug Plans (PDPs) in select PDP regions. This model tests whether offering Part D sponsors programmatic flexibilities under the MTM program, can improve therapeutic outcomes and decrease net Medicare expenditures.

CMS would like to continue to test Part D sponsors' development of robust, targeted, and effective MTM programs through the PDM Model. To do so, CMS intends to waive MTM requirements for targeting, interventions, and engagement, as well as uniformity and accessibility of benefits requirements, for participating Part D sponsors that develop innovative MTM programs (termed MTM+ programs in this RFA). By allowing Part D sponsors to develop MTM+ programs, in lieu of the standard Part D MTM program CMS is testing ways MTM programs may be developed and implemented that improve beneficiary targeting and engagement, with the aim of improving adherence, coordination of care, and understanding of a beneficiary's medication regimens.

Specifically, Part D plan sponsors may apply to CMS to offer MTM+ programs that are more clinically impactful and meaningful, as measured by increased engagement and uptake of MTM interventions by beneficiaries, recommendations by the providers that care for them, improved medication adherence, and decreased Part D costs and Parts A and B costs. Under this flexibility, the current regulatory requirements for standard MTM programs would be waived under the Model, including targeting requirements and document and format requirements.

In their application, Part D sponsors seeking to offer an MTM+ program will propose to CMS how the program targets and engages enrollees in ways that go beyond the defined CMS requirements of "targeted beneficiaries". While we expect Part D sponsors to include the three core elements of traditional MTM (specified chronic conditions, number of drugs, and projected annual drug spending), CMS expects Part D sponsors to design MTM+ proposals that target enrollees using advanced beneficiary characteristics, such as: medication adherence; risk of under- or over-use of medications; medication reconciliation and appropriate utilization for beneficiaries undergoing a transition of care, beneficiaries on specific medications; and beneficiaries with clinical and

socioeconomic characteristics who would benefit from specific engagement with the Part D sponsor.[5]

Part D sponsors must outline the following for approval to offer an MTM+ program in the PDM Model:

- The evidence base and foundational approach of the MTM+ program;
- A coherent, specific MTM+ program design. Given CMS is testing ways to improve medication use, as well as improve medical outcomes, program designs should be specific in what they include and why. These designs may include, but are not limited to, care transition programs, medication reconciliation, chronic condition and disease management, disease-based pharmacist counseling, and medication adherence strategies, among others;
- The targeting criteria for enrollees who are eligible for the MTM+ program (e.g., disease states, risk score, beneficiaries undergoing a transition of care, and any other beneficiary characteristics (number of chronic conditions, number of medications, presence of a medication that requires specific use criteria and other counseling, annual drug spend, etc.);
- The specific way the Part D sponsor will implement the MTM+ program, including how and when enrollees will interact with the MTM+ program, what the enrollee will receive from the Part D sponsor, who will conduct the MTM+ session, and how often the population will be updated;
- The specific engagement plan, including when and how beneficiaries will be engaged, how often will beneficiaries be engaged after an initial discussion, the form and format of any communication from the Part D sponsor to the beneficiary, and how the Part D sponsor will engage with prescribers in helping manage beneficiaries; and
- The proportion of enrollees currently targeted and engaged in the Part D sponsor's current MTM program, the proportion of enrollees who are projected to be targeted for MTM+, and the proportion of enrollees who are projected to be engaged.

Part D sponsors that are also participating in the Enhanced MTM Model may participate in the PDM Model with the same PBPs. However, Part D sponsors that are participating in both models would only be able to offer an Enhanced MTM program, and not an MTM+ program, under this Model.

The test of an MTM+ program under this Model is separate and distinct from the testing of the Enhanced MTM Model because CMS is not providing additional funding (i.e., there will not be

[5] 42 C.F.R. 423.153 defines a "targeted beneficiaries" as enrollees who (i) Have multiple chronic diseases, with three chronic diseases being the maximum number a Part D plan sponsor may require for targeted enrollment. (ii) Are taking multiple Part D drugs, with eight Part D drugs being the maximum number of drugs a Part D plan sponsor may require for targeted enrollment. (iii) Are likely to incur the following annual Part D drug costs: (A) For 2011, costs for covered Part D drugs greater than or equal to $3,000. (B) For 2012 and subsequent years, costs for covered Part D drugs in an amount greater than or equal to $3000 increased by the annual percentage specified in §423.104(d)(5)(iv) of this part

an additional Per-Member-Per-Month payment) to Part D sponsors for the development and implementation of their MTM+ programs.

b. New Flexibilities to Lower Costs for Beneficiaries: Limited initial days' supply and Cost-Sharing Smoothing

Today, Part D sponsors design and implement their pharmacy networks to ensure enrollees have broad and convenient access to their covered Part D drugs. As part of working with network pharmacies, CMS encourages Part D sponsors to propose innovative strategies to provide lower negotiated prices at Point-of-Sale (POS), which may include ensuring the negotiated price is reasonable compared to the acquisition cost. Further, CMS strongly encourages Part D sponsors to decrease pharmacy price concessions throughout their network of pharmacies, including utilizing a lowest-negotiated-price-based and/or performance-based payment arrangement.

As part of working with network pharmacies, this section outlines two optional flexibilities CMS is testing that will allow Part D Sponsors to work with network pharmacies to lower enrollees' cost-sharing for medications and better deliver value to their enrollees:

1. Limited initial days' supply
2. Smoothing of Enrollee Cost-Sharing through All Part D Benefit Phases

Under the Model, Part D sponsors may propose as part of their application to CMS to offer one or both of the following flexibilities:

1. Limited initial days' supply: Part D sponsors may propose to limit the first fill of a new medication to a clinically and operationally feasible time frame of less than a 30-days' equivalent supply for covered Part D drugs where there is a clinical and drug utilization review rationale to do so; and

2. Smoothing of Enrollee Cost-Sharing through All Part D Benefit Phases: Part D sponsors may propose to CMS innovative approaches to improving access to medications, including allowing an enrollee to pay their prescription cost-sharing over time within the course of the Plan Year (e.g., installment payments).

Limited Initial Days' Supply for Treatment Naïve Patients

Under the Model, Part D sponsors may propose to provide treatment naïve patients (i.e., a patient who has not received the specific therapy previously) a trial of the medication through a limited-day supply for the first fill of a new medication based on clinical criteria of the drug and as established by the Pharmacy and Therapeutics committee at the Part D sponsor. In implementing

a Limited initial days' supply program, the Part D sponsor must make clear to CMS, and then to enrollees, which classes are included in this program along with updates as new therapies are introduced. Part D sponsors may choose to incorporate a Limited initial days' supply program as part of a MTM+ program. While this Model component will provide sponsors with additional flexibility to incorporate this Limited initial days' supply into their benefit design, any quantity limits applicable to the limited days' supply are still subject to existing Part D rules and would not otherwise prevent the beneficiary from filling the remainder of the medication once the therapy regimen is established and tolerable. This approach may help Part D sponsors improve care management/coordination programs and the management of drug therapies, including helping to monitor for adverse effects, increasing medication adherence, and decrease waste and beneficiaries' costs through earlier identification of the need for dosage adjustments or treatment regimen changes, among others.

One example of a class of drugs that could be considered for a limited day initial fill is antineoplastic agents. Some studies have found significant adherence risk associated with oral chemotherapy, particularly in the first 30 days of therapy. In addition, some oral chemotherapy agents involve frequent and significant toxicities, which must be monitored. Through their MTM+ program, sponsors can help monitor for serious adverse effects associated with antineoplastic agents when therapy is initiated. When significant adverse effects occur that require a beneficiary to change/discontinue a medication, limiting the initial fill of antineoplastic agents reduces waste, potential exposure to hazardous drugs, and the cost associated with lost therapy days.

Sponsors that propose to offer this flexibility should include in their application: (1) the number of days of medication that will be dispensed (CMS will consider initial fill limits of less than a 30-day equivalent supply); (2) the drug(s) and its defined class that will be restricted to a limited-days' supply for the initial fill; and (3) documentation of the clinical rationale for the selected drug classes.

When establishing the drug classes that they propose to be restricted to a limited days' supply Part D sponsors should evaluate the available marketed package size of the drugs subject to this limitation and establish appropriate days' supply limits consistent with available package sizes. CMS will not approve days' supply limit application proposals that require dispensing pharmacies to break "unit-of-use" or other packaging formats in which the manufacturer's original package is designed and intended to be dispensed to the patients without repacking. In addition, CMS expects that after a limited days' supply is provided to the beneficiary and therapy regimen is established and tolerable, the pharmacy would continue to provide the balance of the prescription and additional refills without further limitations subject to utilization management edits submitted to and approved by CMS during the annual formulary review process subject to those utilization management edits submitted to and approved by CMS during the annual formulary review process.

In analyzing PDE data from 2018, we found more than 90 percent of specialty drug fills were for 30 days' supply or less. Based on this data analysis, we recommend that sponsors use a look-back

period of at least 60 days to identify treatment naïve patients. CMS is also aware that it may be difficult for sponsors to distinguish new prescriptions (treatment naïve patients), therefore a minimum of 108-day look-back consistent with the Part D Prescription Drug Manual, Chapter 6, Section 30.4.3 should be considered.

When determining the cost of the initial fill, the Part D sponsor is required to provide its enrollees access to a daily cost-sharing rate in accordance with §423.153(b)(4). Sponsors must therefore apply the appropriate daily cost-sharing rate, when calculating the beneficiary cost-sharing for the limited initial days' supply.

When designing programs to limit the initial fill, if the claim is rejected by the plan due to days' supply, and the patient does not receive a covered fill of the full days' supply as written, then consistent with 42 CFR § 423.128(b)(7)(iii), the sponsor is required to notify its network pharmacy to distribute a written copy of the standardized CMS pharmacy notice to the enrollee ("Medicare Prescription Drug Coverage and Your Rights", CMS-10147, OMB Approval No. 0938-0975; see also Section 40.12.3 of the Part C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance). In addition, an enrollee, the enrollee's representative, or the enrollee's prescriber has the right to request a coverage determination from the plan for a drug or drugs subject to the days' supply limit, including the right to request an expedited coverage determination.

Upon review of the application, CMS may request additional information regarding the proposal to allow further assessment of whether the proposal as implemented would align with the goals of the Model. CMS will make available templates to collect application materials specific to this component of the Model.

Smoothing of Enrollee Cost-Sharing – Easing the Financial Burden of Medication Costs for Enrollees

Within the structure of the Part D benefit, enrollees pay different cost-sharing for the same drug as they progress through the phases of the Part D benefit (Deductible, Initial Coverage, Coverage Gap, and Catastrophic). For example, the first fill of the drug at the beginning of the calendar year may be subject to a deductible of up to $435 for 2020, followed by a 25-33 percent co-insurance before the enrollee reaches the coverage gap, where they pay 25 percent, followed by a five percent coinsurance when the total out-of-pocket spending exceeds an annual threshold ($6,350 in 2020). Depending on the cost of their medications, the enrollee may reach the catastrophic phase of the Part D benefit with one or two prescription fills—making access to needed medications unaffordable for enrollees.

As part of this Model, CMS is providing Part D sponsors flexibility to establish payment options for enrollees that help them afford their medications. Specifically, through the cost-sharing

smoothing flexibility enrollees could be given the option to pay for all of their medications during the year under a "budget payment plan" (i.e., multiple payments/installments) throughout the calendar year, rather than paying for the total cost-sharing upfront. Enrollees would need to elect to participate in the payment plan (or "cost-sharing smoothing program").

As outlined below, a monthly payment would be created (calculated on a rolling basis), based on the enrollee's medication out-of-pocket costs owed divided by the number of months remaining in the Plan Year. Part D sponsors implementing this flexibility would not be permitted to charge the enrollee an interest rate or additional payments for electing this option and the pharmacy must be reimbursed per the terms and conditions that govern the contract between the Part D sponsor and the pharmacy at the time of dispensing (i.e., the pharmacy must be held harmless and the Part D sponsor must pay the enrollee's cost-sharing at the point of sale).

Part D sponsors implementing the cost-sharing smoothing flexibility would be required to establish the following process with respect to each beneficiary that opts in:

1) For each month in the plan year that the beneficiary elects to participate in the cost-sharing smoothing program, a monthly payment amount would be created by dividing the actual out-of-pocket spending owed by the beneficiary for all of their medications by the number of months remaining in the plan year. All out-of-pocket costs incurred for all Part D drugs once the beneficiary elects to participate in the cost-sharing smoothing program, shall be smoothed in such a way, regardless of the benefit phase in which those costs were incurred.
2) For each subsequent month, the actual out-of-pocket amounts owed for additional Part D medications will be added to the previous month's out-of-pocket spending less any monthly payments received from the enrollee to obtain the total out-of-pocket spending, which will be divided by the number of months remaining in the plan year to calculate an updated monthly payment amount.
3) Once the beneficiary elects to participate in the cost-sharing smoothing program, the pharmacy would no longer charge the enrollee at the point of sale; instead, the plan would directly bill the enrollee their monthly payment amount and pay the enrollee share for any fill to the pharmacy at the point of sale.
4) If the beneficiary elects to participate in the cost-sharing smoothing program and opts out during the year or fails to pay the monthly payment as required, the beneficiary's election in the cost-sharing smoothing program will be terminated and the beneficiary will pay the cost-sharing otherwise applicable for any drugs subsequently dispensed to the beneficiary at the point of sale. In addition, the plan should continue to bill the beneficiary their monthly payment amount for the months remaining in the plan year.
5) Part D sponsors are directed to report cost information on the Prescription Drug Event (PDE) record as if the beneficiary paid the full cost-sharing amount at the point of sale (i.e., patient liability actually owed), not the monthly payment. Additional technical guidance

on the reporting of PDE data may be provided to model participants as part of the implementation of the Model, if deemed necessary.

In the event that an enrollee passes away or gains LIS eligibility before they have completed his or her monthly payments for the plan year, the enrollee and CMS must be held harmless by the Part D sponsor for any unsettled balances. CMS would not be liable for any unsettled balances outside of those assumed as losses in plan bids.

In their application, Part D sponsors must include how they would operationalize the cost-sharing smoothing flexibility process outlined above, including, the enrollee monthly payment calculation methodology, the mechanics of the payment at the pharmacy counter to hold the pharmacies harmless, and the mechanism for handling/collecting unsettled balances. Upon review of the application, CMS may request additional information regarding the proposal to allow further assessment of whether the proposal as implemented would align with the goals of the Model.

c. Part D Rewards and Incentives

Through the PDM Model, CMS is testing the impact of allowing Model participants to propose Part D RI programs that, in connection with medication use, focus on promoting improved health, medication adherence and the efficient use of health care resources. Specifically, CMS is interested in testing how Model participants will leverage rewards and incentives to better manage the provision of the Part D benefit.

Through testing a variety of Part D RI programs, CMS is seeking to (i) encourage greater enrollee education and engagement between enrollees and their chosen Part D sponsor. Notably, the PDM Model will allow Model participants to adopt Part D RI programs that include an adherence metric as part of an enrollee qualifying for the Part D reward or incentive. Likewise, the PDM Model will allow Model participants to adopt Part D RI programs that incentivize switching to generic medications or biosimilars. Importantly, participants will not be permitted to offer Part D RI programs that are conditioned solely on medication adherence or switching.

Instead, Part D sponsors would need to propose a Part D RI program that includes at least one of the four permissible design elements outlined below, in addition to an adherence metric or switching. While the use of an adherence metric, or switching is not allowed for Value Based Insurance Design (VBID) Part D RI programs, CMS is allowing this under the PDM Model because this Model is specifically focused on managing drug spend, and incentivizing medication adherence as a key lever for managing drug costs and improving quality outcomes for beneficiaries.

For example, a Part D sponsor may include in its application a proposal to adopt a Part D RI program under which it would augment its Medication Therapy Management (MTM), or MTM+ program (described in more detail below) by providing a reward and incentive for enrollees both receiving MTM services and being adherent to their prescribed medications. A Part D sponsor that proposes an adherence metric must outline how it defines adherence in its application proposal. Similarly, a Part D plan sponsor that proposes to adopt a Part D RI program that incentivize switching must outline in its application proposal how the proposal will improve affordability, access, and adherence to a clinically- and therapeutically-equivalent generic or biosimilar to the medication prescribed by the enrollee's provider/supplier. CMS will not approve an application proposal that includes an adherence metric, unless the proposal matches with CMS' goals for the Model (i.e., promoting improved health, medication adherence or switching, and the efficient use of health care resources).

Part D sponsors may propose Part D RI Programs based on the guidelines below.

Permissible Part D RI Program Designs Generally

1. Programs designed to target enrollees with specific conditions or enrollees who would benefit from participating in disease state management programs;
2. Programs designed to provide rewards and incentives for enrollees who participate in plan sponsor MTM programs;
3. Programs designed to provide rewards and incentives for enrollees who participate in the receipt of covered Part D vaccines and other drug therapies that focus on preventive health services;
4. Programs designed to enable enrollees to better understand their Part D plan benefit, costs, and clinically-appropriate coverage alternatives, including biosimilars and generics. Specifically, Part D RI programs that provide rewards and incentives to enrollees that participate in educational programs to improve their understanding of their Part D plan benefit, costs, and clinically-appropriate coverage alternatives.

Impermissible Part D RI Programs

1. Part D RI Programs that would reward enrollees for not taking any, or few, Part D covered drugs and vaccines. Part D sponsors may not structure a Part D RI Program to discourage clinically-indicated medication use.
2. Part D RI Programs that would largely serve to market the plan or to encourage beneficiaries to remain with a specific plan based on a reward and incentive. Part D sponsors may not use an RI program to, in any way, choose or solicit healthier enrollees over enrollees who the sponsors believe may be less healthy. Rewards and incentives may not be offered to potential enrollees under any circumstances.

3. RI Programs that discriminate against enrollees based on race, national origin, limited English proficiency, gender, disability, chronic disease, whether a person resides or receives services in an institutional setting, frailty status, health status, or other prohibited basis.
4. Part D RI Programs cannot be used to steer beneficiaries to mail service pharmacies, preferred pharmacies, or any other specific network providers. Rewarding a beneficiary's choice of pharmacy is not an appropriate activity to influence through rewards and incentives, nor should choice of pharmacy negatively affect an enrollee's ability to earn rewards and incentives under a Part D RI Program.
5. Part D sponsors may not, in connection with a Part D RI Program, receive funding, in-kind resources, or any kind of payment provided by a drug manufacturer, nor may the sponsor's Part D RI Program make use of personnel affiliated with a manufacturer, manufacturer-financed coupons or discounts provided to a beneficiary. Further, Part D sponsors may not, in connection with the Part D RI Program, receive funding, in-kind resources, or any kind of payment from pharmacies, nor may a Part D sponsor's program make use of personnel affiliated with a pharmacy, pharmacy-financed coupons, or discounts provided to a beneficiary.

Requirements for Part D RI Programs

Proposed Part D RI Programs must include the following:

1. The goals of each Part D RI Program.
2. The nature and scope of each Part D RI Program, including the criteria for identifying enrollees and the beneficiary engagement methodology.
3. The eligibility criteria that must be met for an individual enrollee to qualify to receive the reward or incentive, including the associated healthcare activity that must be completed for the reward or incentive to be available, and, if eligibility includes an adherence metric, the specific criteria for measuring adherence, and the evidence base to support the clinical appropriateness of the adherence criteria.
4. The type and per unit value of each reward or incentive and the method for providing the reward or incentive to eligible enrollees. (e.g., a gift card with a per unit value of $25 offered quarterly for a total of $100 per year) up to $600 annually per enrollee.
5. The maximum number and frequency of the rewards and incentives that may be obtained by an eligible enrollee per year. The evidence base and theory of change used to develop the reward or incentive and the expected outcomes of the Part D RI Program.

In addition, Part D RI Programs must:

- Be complete by the end of a Plan Year. Part D RI Programs may not allow enrollees to carry over rewards and incentives from one contract year to the next.

- Any rewards or incentives offered under Part D RI programs must be limited to a value that may be expected to impact enrollee behavior and may not exceed the value of the health-related service or activity. Part D sponsors must reasonably establish value for any pharmacist consultation, successful medication adherence, successful formulary compliance, or other CMS-approved health-related activity or service for which they offer rewards and incentives.
- Notwithstanding the limited scope of any potential fraud and abuse waivers of the PDM Model test, which are not being granted as part of the application, Part D RI Programs must comply with all fraud and abuse laws, including, when applicable, the anti-kickback statute and civil monetary penalty prohibiting inducements to beneficiaries.
- Part D RI Programs are prohibited from providing rewards or incentives in the form of cash or other monetary rebates.
- CMS will not approve or will terminate use by a participating plan of Part D RI Programs that largely serve to market the plan or to encourage beneficiaries to remain with a specific plan based on a reward and incentive. Rewards and incentives may not be used to decrease cost-sharing or plan premiums.
- Rewards and incentives must be tangible items that align with the purpose of the Part D RI Program and must directly benefit the enrollee. Part D sponsors have the flexibility to propose what may be offered as a reward or incentive, including gift cards and discount coupons as long as they are not transferable for cash and may not be used to directly or indirectly decrease cost-sharing for medication(s) or plan premiums. A plan's charitable contribution made on behalf of the enrollee does not satisfy the CMS criteria as a permissible reward or incentive because the enrollee who earned the reward does not benefit from such a contribution by the sponsor. The use of points (which are not themselves tangible), however, to purchase a non-cash or cash equivalent reward does satisfy CMS criteria because the points are used by each enrollee to obtain a tangible reward that is of value to the enrollee.
- Part D RI Programs that are designed to be won based on probability, including programs in which an enrollee may earn entries into a lottery or drawing in order to receive a reward or incentive of a significant value, are prohibited.

More generally, CMS will review all proposed Part D RI Programs based on the rationale and theory for the reward or incentive; the population of focus; how the plan defines the value of the reward to total cost of care; and the expected health outcomes and cost and savings effect of its proposed intervention. CMS, in its sole discretion, reserves the right to accept or reject any Part D RI Program proposal.

As part of Model monitoring and evaluation, participating Part D sponsors that offer Part D RI Programs shall submit reports to CMS, in a form and manner and by a deadline specified by CMS any Part D RI Program it offers including the total expected and actual costs of the Part D RI Program; the value of the reward and incentive and how the value was derived; the number of

enrollees targeted under the Part D RI Program; the number of enrollees that received the reward or incentive, including trends over time; and any demographic or other information about the types of enrollees engaged; and any evaluation of the effectiveness of the program.

Additionally, if in the course of CMS monitoring it is determined that a Part D sponsor is not operating its Part D RI Program in compliance with the approved program, CMS may impose sanctions or civil money penalties on the Part D sponsor in accordance with §423.752(a)(5).

Part D Rewards and Incentives Overlaps with the Enhanced MTM and VBID Models

If Part D Sponsor is also participating in the Enhanced MTM, the Part D Sponsor may not conduct a Part D RI Program under this Model. If Part D Sponsor is also participating in the Medicare Advantage Value-Based Insurance Design (VBID) Model, any Part D RI Program should comply with the requirements of this Model.

d. Reduction or Elimination of Cost-Sharing on Generic Drugs and Biosimilar for Low-Income Subsidy Beneficiaries

The President's FY 2020 Budget[6] outlines a proposal to eliminate cost-sharing on generic drugs and biosimilars for low-income beneficiaries. The President's Budget proposal encourages the use of higher value products among LIS beneficiaries by reducing cost-sharing to $0 for generics, biosimilars, and preferred drugs that are multiple source.

Consistent with a stated Model goal of encouraging the use of lower-cost, clinically-effective generic and biosimilar drugs, and to test the impact of reduced or eliminated cost-sharing for these therapies, CMS will permit Model participants to reduce cost-sharing for generic and biosimilar drugs for LIS beneficiaries to an amount below the statutory maximum copayment and still receive low-income cost-sharing subsidy (LICS) payments that reflect the difference between the plan's cost-sharing amount and the LIS statutory maximum copayment amount.

In CY 2021, this programmatic flexibility is available to standard or alternative Part D coverage (defined standard, actuarially equivalent standard, basic alternative, and enhanced alternative plans). As part of their application, Part D sponsors must also submit a supplemental file (Part D Payment Model LIS Cost-Sharing Reduction File) that identifies which Part D drugs they are proposing to reduce or eliminate the cost-sharing for LIS beneficiaries.

[6] Department of Health and Human Services. https://www.hhs.gov/sites/default/files/fy-2020-budget-in-brief.pdf.

The expectation is that Part D plan sponsors would utilize this flexibility when the net cost of the generic or biosimilar is lower than the branded therapy or biologic.

Technical guidance on the necessary updates to Prescription Drug Event data will be provided to Model participants as part of the implementation of the Model. Model participants wishing to use this flexibility must reflect any cost changes in their Part D bids consistent with the Model-specific guidance issued by CMS.

e. Plan Timeliness for Standard Initial Coverage Determinations

Regulations at Subpart M of 42 C.F.R. Part 423 require that for standard requests for drug coverage, Part D plan sponsors must notify the enrollee (and the prescribing physician or other prescriber involved, as appropriate) of its determination as expeditiously as the enrollee's health condition requires, but no later than 72 hours after receipt of the request. Sponsors have stated that these timeframes can prove challenging when additional information is needed from the prescriber to determine whether coverage criteria are met, leading to unnecessary denials and delays in beneficiary access to needed medications.

The PDM Model will permit Part D sponsors to increase the standard coverage determination timeframe to 96 hours for requests for drug coverage to allow model participants, prescribers, and enrollees to increase adherence to medications at first fill, increase initial determination approvals, and decrease re-determinations. This programmatic flexibility may be implemented by any Part D sponsor participating in the Model, and would not apply to (a) expedited requests; (b) exceptions requests; or (c) requests for payment. This programmatic flexibility would enable CMS to monitor the rate of approvals for standard initial coverage determinations for drug coverage relative to a comparison group of Part D plan sponsors that are not in the Model to inform future policy direction.

As Model participants are assuming greater risk for Part D spending, and because of interest expressed by Part D plan sponsors in a 96-hour window for standard initial coverage determinations, testing the impact of different response timelines for coverage determinations and notification methods, while still requiring expedited reviews when warranted consistent with existing regulations, may allow CMS to understand innovations around utilization management and implement best practices that allow engagement of both the enrollee and the prescriber. This includes ensuring the enrollee and prescriber are aware of coverage for the prescribed medication(s), alternative therapies, and costs of each, including in the coverage gap or catastrophic spending phase.

CMS is interested in understanding approaches that participating Part D plan sponsors currently take that provide for a positive enrollee and prescriber experience while allowing for appropriate management of drug therapies.

f. Additional Flexibility under the *De Minimis* Policy

The availability of zero-premium coverage for LIS enrollees fluctuates from year to year, potentially exposing Part D LIS enrollees to higher costs unless they change into another zero-premium plan (either voluntarily or being automatically reassigned by CMS). Part D plan sponsors may voluntarily waive the portion of their monthly adjusted basic beneficiary premium that is a *de minimis* amount above the LIS benchmark for eligible individuals, and CMS will not reassign enrollees away from these Part D sponsor plans.

To decrease any movement of LIS beneficiaries for Model participants, CMS may allow Model participants to waive a greater *de minimis* amount than non-model participants. Any increase in amount participating Part D plan sponsors, in addition to a potential variation in the amount for Model participants, may waive under the *de minimis* policy will be announced in the annual release of Part D National Average Monthly Bid Amount and other Part C & D bid information and operational guidance**.**

2.3 Changes to Model Design in Current or Future Model Years

CMS retains 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. Reconciliation for the final Model year, and payment of any performance-based payments or assessment of any penalties is anticipated to occur in 2025 as part of 2024 reconciliation. CMS, in its sole discretion, may terminate the Model before December 31, 2024.

3. Quality and Performance Monitoring

As part of both Model implementation and evaluation, CMS will monitor the impacts of the Model on cost and quality. Specifically, CMS will monitor the Model's impact on Part D spending, as well as on how beneficiary access to covered Part D prescription drugs and the affordability of those prescription drugs is maintained or enhanced. A description of some dimensions CMS intends to monitor through the Model are below:

- **Prescription drug list price:** CMS may monitor and assess the extent to which list prices for Part D drugs change over the course of the Model;
- **Prescription drug net price:** CMS may monitor and assess the extent to which prices net of all direct and indirect remuneration are different between Model participants and non-participants;
- **Prescription drug choice, quality, and access**: CMS may monitor and assess any changes or differences in formularies, complaints from 1-800-MEDICARE and the Medicare Complaint Tracking Module, Stars ratings, and appeals and grievances for Model participants and non-participants;

- **Part D drug utilization:** CMS may monitor and assess prescription drug event claims to determine the types and classes of medications that are utilized, including specialty-tier, non-specialty-tier brand, and generic, by enrollees in participating and non-participating plans;
- **Part B drug utilization and spending:** CMS may monitor any changes in Part B drug utilization and spending for enrollees in participating versus non-participating plans. CMS will investigate any material shift in utilization from Part D drugs to Part B drugs or Part B to Part D drugs for an organization that is participating in the Model;
- **Parts A and B spending:** CMS may monitor and assess any differences in Parts A and B spending for enrollees in participating and non-participating plans;
- **Part D Bids and Payments:** CMS will review Part D bid data, including both the direct subsidy and prospective federal reinsurance subsidy, to reconciled, actual spending for Model participants and non-participants;
- **Part D Premiums:** CMS may monitor and assess any Part D premium trends for Model participants and non-participants;
- **Pharmacy Network:** CMS may monitor and assess the pharmacy network that participating and non-participating plans' enrollees utilize for their medications; and
- **Part D Rewards and Incentives Programs:** CMS will monitor and assess any changes in prescription drug utilization secondary to any Reward and Incentives programs; and other items as deemed appropriate to promote compliance with all model terms, beneficiary protections, and program integrity. Additionally, the Model will monitor and assess potential risks associated with Part D RI Programs by requiring participating plan sponsors to provide details specific to their RI programs.

While CMS will attempt to utilize existing data sources for both Model implementation and evaluation activities, Model participants will be required, where appropriate, to provide information to CMS, such as for any Part D Rewards and Incentives Program.

3.1 Enrollee Protections and Oversight

CMS will conduct regular monitoring to review Model participant compliance with the terms of the Model test. CMS will monitor for compliance using existing data sources to the extent practicable, and may seek plan-provided data or conduct site visits, particularly in response to high levels of complaints or other indicators of poor performance. CMS will closely monitor Model implementation, to ensure that plan performance is consistent with Model rules and approved proposals, and that the Model is not leading to any adverse beneficiary outcomes. This will include, but not necessarily be limited to, observing existing metrics of beneficiary access, outcomes, and satisfaction, and monitoring for increased beneficiary questions or complaints through 1-800-MEDICARE or the https://www.medicare.gov website. CMS will also monitor the impact the Model has on other CMS initiatives, such as the Part D Star Ratings.

CMS reserves the right to investigate an organization if there is evidence that indicates that the

organization's participation in the Model is adversely impacting enrollee quality of care, and exercise all available remedies in appropriate instances, including potential termination from the model test.

4. Evaluation

CMS will use an independent contractor to conduct an evaluation of the PDM Model, which will examine the Model's implementation and assess the Model's impact on Medicare spending and the quality of care. All Model participants will be required to participate in evaluation activities. CMS anticipates primarily relying on publicly available and existing data sources in the evaluation of the Model. In certain situations, however, Model participants will be required to cooperate with primary data collection activities, which may include participation in surveys, interviews, site visits, and other activities that CMS determines necessary to conduct a comprehensive formative and summation evaluation. When the evaluation uses non-publicly available data (e.g. certain bid data), CMS will report results at an aggregate-level to avoid the disclosure of private and sensitive data of specific Model participants.

5. Application Process and Selection

Part D sponsors interested in applying to participate in the PDM Model should submit their application for PDPs and/or MA-PDs by no later than **April 24, 2020, 11:59 PM ET**. The application is accessible on the Model's website at: https://innovation.cms.gov/initiatives/part-d-payment-modernization-model/.

Questions regarding the Model or application process may be sent by email to PartDPaymentModel@cms.hhs.gov. While CMS will not share the source of the question, CMS may publicly share questions and responses or compile them into a Frequently Asked Questions compendium to ensure that all applicants have access to information regarding the Model and the application process.

To participate in the model, applicants must follow the following process:

Step 1: CMS Feedback (March 2020 through April 2020)

In an effort to provide Part D sponsor support for the PDM Model, CMS will provide feedback on a rolling basis between the release of this RFA through April 24, 2020. CMS expects to engage with Part D sponsors to ensure the success of the Model in regards to Model participation, Model requirements, and enrollee protections. By statute, CMS cannot interfere in Part D sponsor negotiations with manufacturers and pharmacies, and CMS will not offer any guidance beyond that offered in this RFA.

Step 2: Application (Due April 24, 2020, 11:59 PM ET)

Using the Application provided by CMS through the Model's website, eligible Part D sponsors may apply with one or more stand-alone PDP(s) in a region and must include all of their stand-alone PDP plan benefit packages (PBPs) in that Part D region. Eligible MA Organizations applying with one or more MA-PD PBP(s) must identify the PDP region or regions that the PBP(s) are offered in and must include all MA-PD plans with service areas that include those PDP region(s).

CMS will use the application process to capture concise, complete applications from Part D sponsors on all of their proposed Model components. Part D sponsors are encouraged to provide specific, clear answers in their application that directly state what the plan proposes to do, for whom, how, and when. Where applicable, a supplemental document or presentation that better defines the overall narrative and specifics of the program may be uploaded. After the Application has been submitted, CMS will review applications and reach out to Part D sponsors for clarity, additional information, or to request changes.

After review, CMS will provide applicants with a provisional approval by April 2020 for Model participation. Of note, Model participant selection is not competitive. CMS does not intend to set a maximum number of qualified Part D sponsors participating in the Model test. CMS also reserves the right to reject any organization, PBP, or proposal to preserve the integrity of the Medicare program, the welfare of enrollees, or the efficient and advantageous administration of the Model.

In accordance with authorities granted in Section 1115A(d)(2) of the Social Security Act, there is no administrative or judicial review of its selection of organizations, sites, or participants to test models. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to this RFA; all costs associated with responding to this RFA will be solely at the interested party's expense. There is no requirement to respond to this RFA, as participation in the Model is voluntary.

Step 3: Bid Submission (June 1, 2020)

A provisionally approved Part D sponsor will include participation in the Model, and all Model components it is participating in, as part of submitting its plan benefit package(s) to CMS by June 1, 2020. Part D sponsors must follow all bid guidance as provided by CMS.

In addition, provisionally approved Part D Sponsors will be required to confirm their participation in the Model by the bid submission date of June 1, 2020 concurrent with and as part of their plan bid submission. In addition to the bid submission requirements, Part D sponsors that were provisionally approved must notify CMS in writing by June 1, 2020 of any changes from their provisionally application, including changes to participating PBPs. Part D sponsors should submit one application per contract.

5.1 Part D Bidding Guidance

Through this RFA, CMS is providing CY 2021 guidance for Model applicants based on identified interactions with the Part D plan sponsor bids. This guidance only serves to augment existing CMS guidance for the purposes of the Model test, including Part D Rewards and Incentives, LIS cost-sharing, MTM+ programs, and model settlement payments. CMS is providing guidance on the following:

- Part D gain/loss margin;
- Part D bid documentation requirements;
- PDM Model settlement and DIR;
- PDM Model settlement and plan gain/loss margin; and
- PDM Model settlement and Medical Loss Ratio Calculation.

The following sections provide commentary and examples of how the PDM Model will integrate with the current Part D financial cycle.

The Part D Financial Cycle and Integration with the PDM Model

The PDM Model is a retrospective risk settlement based on establishing a counterfactual of Part D federal reinsurance subsidy spending. Said differently, the Model measures the ability to manage expenses in the Catastrophic Phase of the Part D benefit, specifically federal reinsurance, relative to industry benchmarks and not the ability to estimate future costs captured in a Part D bid. However, the PDM Model settlement will interact with various components of the current Part D bid and reconciliation cycle. The purpose of this section is to describe this current Part D financial cycle and provide context and guidance on the potential interactions with the PDM Model settlement and Part D plan sponsor bids.

Part D Gain/Loss Margin

Gain/loss margin refers to the additional revenue requirement beyond prescription drug costs and non-benefit expenses. Part D plan sponsors meet gain/loss margin requirements at the bid level and at an aggregate level. PDM Model participants that offer Part D Rewards and Incentives, reduce LIS cost-sharing below the statutory maximum copayments and/or MTM+ programs, must reflect any associated costs in their Part D bid.

Part D Rewards and Incentives costs should include: (i) any induced utilization of a covered Part D drug in the Part D bid; and (ii) administrative costs and reward and/or incentive costs as a Part D non-benefit expense.

MTM+ program costs must still be included as administrative costs.

Additionally, to the extent necessary, participating plan sponsors may request margin rule exceptions to account for losses incurred from covering LIS cost-sharing consistent with the current bid instructions.

Part D Bid Documentation Requirements

Model participants should make reasonable estimates of the expected impact from Model participation, including, but not limited to, any projected changes to direct and indirect remuneration (DIR), additional administrative expenses and incurred Part D covered drug costs related to any Part D RI programs, and formulary changes.

Bid supporting documentation and build-up should include program descriptions and any analyses or projections of program costs and savings to the extent they are available. In future model years, we will provide guidance on the expectation to document previous year program cost and saving analyses.

Treatment of Model Gains or Losses for the Purposes of DIR Reporting

PDM Model settlements, like other CMS payments to plans, are not considered direct or indirect remuneration.

PDM Model settlement and plan gain/loss margin

For the purposes of calculating projected Part D gain/loss margin, any impact from expected model settlement amount does not need to be explicitly included in projected gain/loss margin. For future model years, with an expected settlement at the time of bid, actual gain/loss margin would reflect model settlement amounts for that base period as revenue reported on Worksheet 1.

PDM Model settlement and Medical Loss Ratio (MLR) Calculation

All PDM Model settlement payments are not to be included in the MLR denominator as revenue for purposes of the MLR calculation. All expenditures related to Part D RI programs should be treated as quality improvement activities.

Prescription Drug Event (PDE) Submission

If a participating plan has an approved proposal to reduce cost-sharing for generic drugs and

biosimilars for an LIS beneficiary below the statutory maximum LIS cost-sharing, this is done after covered plan payments (CPP) and Low-Income Cost-Sharing Subsidy (LICS) are calculated on the PDE. The Patient Pay Amount on the PDE becomes the reduced cost-sharing amount. The difference between the original Patient Pay amount after the application of any supplemental coverage the plan offers outside of the PDM flexibility and the reduced cost-sharing amount after the application of the PDM flexibility (i.e., the LIS cost-sharing buy-down under the PDM Model) must be reported on the PDE in the Patient Liability Reduction due to Other Payer Amount (PLRO). Model participants must comply with all other PDE reporting rules, such as the requirement that EA supplemental benefits be applied before gap discount and before LIS, as established by CMS for Part D plans not participating in the Model. Additionally, in Plan-to-Plan (P2P) situations, the LIS cost-sharing buy-down under the PDM Model (reported as PLRO) will not be considered as actual LICS in the LICS reconciliation when the submitting contract offers an enhanced alternative benefit and the submitting contract is not the Contract of Record.

5.2 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 requirements of the Model, as well as any policy documents issued by CMS to govern the Model test. CMS expects to finalize and execute the addenda in September 2020 concurrently with the signing of other Part D contract documents. Participating PDP sponsors and MA-PD plans 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 program and payment waivers of statutory or regulatory requirements, and any limitations to such program and payment waivers
- Requirements for participation in CMS monitoring and evaluation activities

5.3 Timeline

The table below outlines the timeline for the application period for the PDM Model:

Date	Milestone
March 2020	PDM Model – CY 2021 Request for Application and Application Portal released.
March – May, 2020	CMS provides feedback and technical assistance to Part D sponsors.
April 24, 2020	Completed Application due to CMS by 11:59pm EST.
May 2020	CMS completes review of applications and provides provisional approval to Part D sponsors for inclusion in their CY 2021 plan benefit package.
June 1, 2020	CY 2021 MA and Part D Bids Complete.
September 2020	Contract addenda for model participation executed.
October 2020	Communication of benefits under the Evidence of Coverage.
January 1, 2021	CY 2021 performance period of the PDM Model begins.

5.4 Withdrawal of Application

Applicant Part D sponsor seeking to withdraw an entire application or requesting to modify a pending or preliminarily approved application should submit a written request on the 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 PartDPaymentModel@cms.hhs.gov.

Prior to bid submission, CMS may allow incremental changes to provisionally approved interventions or Model components so Part D Sponsors may incorporate feedback from CMS or to otherwise improve the application to meet their goals for the Model. After application and bid submission on June 1, 2020, CMS will only allow changes of a type typically allowed for Part D benefits after bid submission, such as those required in response to CMS bid desk review findings, or made during rebate reallocation. Allowance of changes to preliminarily approved interventions is a matter of CMS discretion, and CMS may require resubmission of actuarial documentation to account for proposed changes.

5.5 Amendment of RFA

CMS may modify the terms of the 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.