Centers for Medicare & Medicaid Services

Center for Medicare & Medicaid Innovation

Part D Senior Savings Model

CY 2022 Request for Applications for

Part D Sponsors

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1. Background and General Information

1.1 Model Scope and General Approach

The Centers for Medicare & Medicaid Services (CMS) is seeking applications for a voluntary model (the Part D Senior Savings Model, or "the Model") that tests the impact on the affordability, access, and adherence of applicable drugs if Part D sponsors, through Model-eligible enhanced alternative standalone prescription drug plans (PDPs) and Medicare Advantage (MA) plans that offer prescription drug coverage (MA-PDs), provide a Part D benefit design that offers standard, predictable copays in the deductible, initial coverage, and coverage gap phases of the Part D benefit.[1] This request for applications (RFA) for Part D sponsors outlines Model design elements, Model eligibility criteria, and additional Model details for Part D sponsors interested in applying to participate in Contract Year (CY) 2022. Part D sponsors wishing to participate must apply for participation in the Model annually. CMS is conducting this Model through the Center for Medicare and Medicaid Innovation (CMS Innovation Center) under Section 1115A of the Social Security Act.

General Approach

In order to directly address the high out-of-pocket costs that beneficiaries pay for insulin, especially in the coverage gap phase of the Part D benefit, CMS is testing the impact of a voluntary Part D Model that offers beneficiaries an increased choice of enhanced alternative Part D plan options that offer predictable out-of-pocket costs for a broad set of formulary insulins.

CMS is testing this Model for five plan years, which began on January 1, 2021. The Model is limited to applicable drugs that are, or contain, a drug classified as insulin in the American Hospital Formulary Service (AHFS) Drug Information or the DRUGDEX Information System compendia and are labeled by pharmaceutical manufacturers that apply to participate and voluntarily agree to the terms of the Model (hereinafter "Model drugs" or "Model insulins").

Based on this Model design, beneficiaries have the option to enroll in prescription drug plans offered by Model-participating Part D sponsors that offer an enhanced Part D benefit design that provides stable, predictable copays, set at a maximum of $35 for a one month's-supply, that applies in the deductible, initial coverage, and coverage gap phases, for a broad set of Model insulins (referred to herein as "Model-Specific Supplemental Benefits").

Current State Outside of Model and Within Model Test

[1] "Applicable drug" is defined in SSA 1860D-14A(g)(2) as a covered Part D drug that is (A) approved under a new drug application under section 505(b) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (other than, with respect to a plan year before 2019, a product licensed under subsection (k) of such section 351); and (B)(i) if the PDP sponsor of the prescription drug plan or the MA organization offering the MA-PD plan uses a formulary, which is on the formulary of the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in, (ii) if no formulary is used, for which benefits are available; (iii) or is provided through an exception or appeal.

Outside the Model, if a beneficiary receives prescription coverage as part of his or her MA plan or through a standalone PDP, the Part D sponsor may choose to offer supplemental benefits that decrease out-of-pocket costs relative to basic Part D coverage. While a Part D sponsor could also offer these supplemental benefits in the coverage gap phase of the benefit, if it does, the pharmaceutical manufacturer of an applicable drug only contributes its 70 percent discount on the amount remaining ***after*** the plan's supplemental benefit is applied. This financial disincentive historically resulted in few Part D sponsors offering supplemental benefits to beneficiaries in the coverage gap for applicable drugs, resulting in a structure where beneficiaries' out-of-pocket costs in the coverage gap were higher relative to the initial coverage phase and beneficiaries had few to no Part D plan choices that offer a supplemental coverage option to lower those costs.

Through this voluntary Model, CMS is testing the impact of allowing Part D sponsors to offer enhanced alternative prescription drug plans with supplemental benefit coverage in the coverage gap, for certain Model drugs (referred to herein as "Plan-Selected Model Drugs"), where the supplemental benefits apply **after** Model-participating manufacturers provide the 70 percent discount, thereby removing a key financial disincentive. The changes to supplemental benefits in this Model only apply to those enrollees who do not qualify for the low-income cost-sharing subsidy (non-LIS) and utilize a Model drug for which the plan provides supplemental benefits.

The voluntary Model's performance period for CY 2021 participating plans began on January 1, 2021, and CMMI will assess potential improvements to medication adherence during the five plan years of the Model for applicable drugs, over both the short- and long-term, and any impacts on Part A, Part B, and Part D utilization resulting from altering the financial obligations of Part D sponsors and manufacturers to give non-LIS Medicare Part D enrollees a stable, predictable copay set at a maximum of $35 for a one-month's supply for certain insulins. For Part D sponsors approved to participate for CY 2022, the voluntary Model's performance period for CY 2022 begins on January 1, 2022 and concludes on December 31, 2022.

To enable broad Part D sponsor participation in order to provide beneficiaries with a choice of Part D plans that offer lower prescription out-of-pocket costs for Model drugs, for CY 2021 and CY 2022, if the Part D sponsor prospectively elects the option, CMS will apply a narrower first threshold risk corridor for Model plan benefit packages (PBPs) that have a statistically higher level of insulin-dependent diabetic beneficiaries than the average in similarly designed Part D plans (i.e., standalone PDPs; MA-PDs; C-SNPs; or I-SNPs). Additionally, through the Model, CMS is testing the impact on medication adherence of enrollees of Part D sponsors offering Part D Rewards and Incentives (Part D RI).

1.2 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.

1.3 Waiver Authority

Under Section 1115A(d)(1) of the Act, the Department of Health and Human Services ("the Department") may waive such requirements of Titles XI and XVIII and of Sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5) of such section) as may be necessary solely for purposes of carrying out section 1115A with respect to testing models described in section 1115A(b).

1.4 Medicare Program and Payment Waivers

In support of this Model, the Department has waived certain requirements under Title XVIII of the Act and its implementing regulations for Model participants for purposes of testing the Model. The Department similarly intends to waive certain requirements under Title XVIII of the Act and its implementing regulations for Part D sponsor participants in the Model for CY 2022. No waivers of any kind are being issued in this document, which merely describes the waivers contemplated at this time for Part D sponsor participants in the Model and new manufacturer applicants that join the Model. Programmatic waivers under consideration include the following:

- Section 1860D-14A(c)(2), Special Rule for Supplemental Benefits, and 42 C.F.R. § 423.2325(e), to waive the following requirement: "where an applicable beneficiary has supplemental benefits with respect to applicable drugs under the prescription drug plan or MA-PD plan that the applicable beneficiary is enrolled in, the applicable beneficiary shall not be provided a discounted price for an applicable drug under this section until after such supplemental benefits have been applied with respect to the applicable drug." This will allow supplemental benefits to apply to the discounted price after the manufacturer coverage gap discount is applied to a Model drug;
- Section 1860D-15(e)(3)(C)(i)(III) and 42 C.F.R. § 423.336(a)(2)(ii)(A)(3) to allow for the first threshold risk percentage to be narrowed to 2.5 percent rather than 5 percent for a Model PBP that has elected the narrowed risk corridor and that has a proportion of insulin-dependent enrollees that is at least one standard deviation greater than the average proportion of insulin-dependent enrollees in all Model-eligible enhanced alternative PBPs of the same plan type – i.e., standalone PDPs, MA-PDs, C-SNPs, or I-SNPs;
- 42 C.F.R. § 423.329(d)(1) to the extent necessary to calculate the low income cost-sharing subsidy for a Model drug based on the cost sharing of the formulary tier(s) for the Model drug without regard to any Model-Specific Supplemental Benefits for such drug;
- 42 C.F.R. §423.578(a) to the extent necessary to permit Part D sponsors to exclude from their tiering exceptions process for Model PBPs any requests to apply Model-Specific Supplemental Benefits to any applicable drug that is, or contains, a drug classified as

insulin in American Hospital Formulary Services (AHFS) Drug Information or the DRUGDEX Information System compendia;

- Section 1860D-11, to the extent necessary solely to permit Part D sponsors to add Plan Selected Model Drugs at any time during the plan year, consistent with existing Part D formulary requirements;
- Rules for calculating the Star Ratings for a Part D sponsor in 42 C.F.R.§§ 423.182-423.186 and 42 C.F.R. 422.162-422.166 to the extent necessary to permit CMS to adjust the rules for calculating the Star Ratings for Part D Sponsors participating in the PDSS Model to protect against a statistically significant negative impact to the Part C and D Star Ratings for MA-PDs and stand-alone PDPs that are not participating in the Model when the impact is directly attributable to participation in the Model;
- Section 1860D-15(f) to the extent necessary to permit CMS to use all Part D bid and payment data for purposes of conducting and evaluating the Model test.

For Manufacturer applicants that join the Model in 2021[2]

- 42 C.F.R. § 423.2315(c)(3), but only as to a renewal of the Underlying Contract that would, in the absence of the Addendum, occur for a one-year period on January 1, 2022; and
- Section 1860D-14A(a) to the extent that the Addendum is a modification to the model agreement for use under the Medicare Coverage Gap Discount program and to the extent necessary to permit the Department and participating Manufacturers to timely execute the Addendum without the consultation and comment.

1.5 Fraud and Abuse Waivers

As noted above, for this Model and consistent with the standard set forth in Section 1115A(d)(1), the Department may consider issuing waivers of certain fraud and abuse provision in Sections 1128A, 1128B, and 1877 of the Act for CY 2022. Fraud or abuse waivers are not being issued in this document. The Department issued a fraud and abuse waiver (set forth in separately issued documentation) which is limited to certain Part D Sponsors in the Model and provided all waiver conditions are met. 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 any such separately documented waiver issued pursuant to Section 1115A(d)(1) specifically for the Model, as may be amended from time to time (e.g., to reflect programmatic changes). Such waivers apply solely to the PDSS Model and could differ in scope or design from waivers granted for other programs or models.

[2] Waivers applicable to existing manufacturer participants in the Model can be found in the CY2021 PDSS Manufacturer Contract Addendum, available on the Model website here: https://innovation.cms.gov/files/x/partd-seniorsav-mnfr-addendum.pdf.

2. Description of Model

2.1 Purpose and Concept

The current Part D defined standard benefit design includes four coverage phases: (1) deductible; (2) coverage up to a defined initial coverage limit; (3) coverage gap; and (4) catastrophic. Based on the defined standard design, Part D sponsors may offer four types of prescription drug plans to beneficiaries: (1) defined standard plans; (2) plans that are actuarially equivalent to the defined standard; (3) basic alternative plans; and (4) enhanced alternative plans.

For enhanced alternative prescription drug plans, through which the majority of Part D enrollees receive their Part D benefit, Part D sponsors provide supplemental benefits that offer enhanced coverage relative to basic Part D plan types. Beneficiaries have the option to choose one of these enhanced plans based on the differential design and additional benefits. The additional coverage is a supplemental benefit and wholly added onto the plan's premium for providing basic Part D coverage. Beneficiaries who elect a plan with enhanced coverage either pay for the additional benefits through premiums or, in the case of an MA-PD, may have some or all of the premium paid for by the government through MA rebates.

Today, beneficiaries with Part D prescription drug coverage face high out-of-pocket costs for some applicable drugs, especially in the coverage gap phase of the benefit. Non-LIS beneficiaries will generally pay a deductible initially, move to a copay for medications up to the initial coverage limit, then pay a 25 percent co-insurance in the coverage gap phase. Non-LIS beneficiaries with true out-of-pocket costs (TrOOP) beyond the out-of-pocket threshold generally pay a 5 percent co-insurance in the catastrophic phase.

As prescription drug list and negotiated prices have continued to rise, beneficiaries' out-of-pocket costs have continued to increase. This leads to beneficiaries having to forgo or ration their use of the medications they need.

While Part D sponsors outside the Model today can, and do, offer enhanced coverage in the coverage gap phase for some covered Part D drugs, there is a financial disincentive to doing so for applicable drugs that receive a manufacturer coverage gap discount. This results in Part D sponsors outside the Model offering Part D plans with limited to no supplemental coverage in the coverage gap for those drugs and beneficiaries paying 25 percent of the full negotiated price. This decrease in medication access and affordability, which results in a decrease in adherence, leads to the short- and long-term deficits in care that CMS is attempting to address through the Model.

Coverage Gap Calculation Examples Outside the Model

Today, outside the Model, pharmaceutical manufacturers provide a discount to non-LIS Part D enrollees of 70 percent of the negotiated price of their applicable drug(s), while the enrollee is in the coverage gap phase of the Part D benefit.

Example 1 - Coverage gap payments for an applicable drug with a $500 negotiated price and no supplemental benefits

First, based on the special rule for supplemental benefits, any supplemental benefits offered by the plan apply first. Because the plan design in this example does not offer supplemental benefits to reduce the cost-sharing for this applicable drug, the manufacturer's discount applies to the full negotiated price.

The manufacturer's coverage gap discount is a 70 percent discount on the negotiated price, or in this example, 70% of $500, which is $350. Beneficiaries pay approximately 25 percent of the negotiated price, which for simplicity and illustrative purposes is $125 (25% x $500 = $125). The Part D sponsor's liability is the remaining 5 percent (5% x $500 = $25). To summarize this example, when a Part D PBP does not offer supplemental benefits in the gap, the breakdown of who pays what is: Manufacturer: $350, Beneficiary: $125, and Plan: $25.

Today Part D sponsors, through their enhanced alternative prescription drug plans outside the Model, are able to design a benefit that reduces beneficiary costs through including supplemental benefits. However, under section 1860D-14A(c)(2) of the Act, if a plan offers supplemental benefits for applicable drugs in the coverage gap outside the Model, the special rule for supplemental benefits applies, which means that the plan's supplemental benefit is applied first to the full negotiated price, with the manufacturer's discount applying next and the beneficiary paying the remaining amount. The below example is designed to illustrate the financial disincentives that this special rule creates for Part D sponsors and beneficiaries.

Example 2 - If a plan wanted to offer a reduced copay of $35 in the coverage gap outside the Model for the same $500 applicable drug

First, based on the statutory special rule for supplemental benefits, the manufacturer's discounted price is not provided until **after** the supplemental benefits are applied. The manufacturer's discount is calculated from the beneficiary's liability, which in this scenario is the $35 copay. To reach the $35 beneficiary liability, the plan would need to assume liability of $465 first. The resulting amount left is $500 minus $465, or $35, which the manufacturer would provide a 70 percent discount on (70% x $35 = $24.50). The beneficiary would then pay the remaining $10.50, for a total breakdown of $465 plan liability, $24.50 manufacturer discount, and $10.50 beneficiary payment. We also note a plan could attempt to reach a net $35 beneficiary payment in this example in a similar way. The scenario depicted is meant to illustrate a realistic coverage gap example that is in line with existing Part D coverage gap program guidance.

The increased plan liability, from $25 in Example 1 to $465 in Example 2, represents the current financial disincentive for Part D sponsors to offer supplemental benefits in the coverage gap for applicable drugs in enhanced alternative plans outside the Model. Because any increase in Part D sponsor liability would increase plan premiums, a limited number of Part D sponsors currently offer enhanced coverage in the coverage gap outside the Model (and only for a limited set of

applicable drugs). As a result, beneficiaries have limited to no plan choices that offer them enhanced coverage for the medications they need, in this case insulin. This Model tests whether increasing access, affordability, and adherence to Model drugs can address potential deficits in care that result from decreased use of medications leading to increased Medicare Part A, Part B, and Part D utilization and costs, and worse health outcomes for beneficiaries.

2.2 Model Design Elements, Plan Eligibility, and Geographic Scope

CMS is testing a voluntary Model for Part D sponsors and pharmaceutical manufacturers available for participation in all states and territories. This Model began on January 1, 2021, and has participating plans in all 50 states, D.C., and Puerto Rico for CY 2021. The Model tests how removing a current financial disincentive in the Part D benefit design and manufacturer coverage gap discount program may result in Part D sponsors offering beneficiaries enhanced alternative Part D plans with stable, predictable copays for Plan-Selected Model Drugs, for non-LIS enrollees, in the deductible, initial coverage, and coverage gap phases of the Part D benefit.

CMS is testing this Model for applicable drugs that are, or contain, a drug classified as insulin in the American Hospital Formulary Service (AHFS) Drug Information or the DRUGDEX Information System compendia and are labeled by pharmaceutical manufacturers that apply to participate and voluntarily agree to the terms of the Model (previously defined as Model drugs or Model insulins). This includes all dosage forms as well as any drugs that meet the criteria for a Model drug and are introduced during a plan year, when labeled and marketed by a pharmaceutical manufacturer participating in the Model. The Model website will list the manufacturers that have agreed to participate in the Model for CY 2022 and the National Drug Codes (NDCs) for all Model drugs.

All current CMS program regulations and guidance applies, including formulary design, except as otherwise waived for purposes of the Model. Part D sponsors' participating PBPs must include at least one vial dosage form and one pen dosage form of each of the pharmacologically and pharmacokinetically different types of Model insulins, when available - rapid-acting, short-acting, intermediate-acting, and long-acting – at a maximum **$35 copay for one month's supply**, for both pen and vial dosage forms – in the deductible, initial coverage, and coverage gap phases of the benefit.

In keeping with the spirit and aims of the Model, Part D sponsors that choose to participate are strongly encouraged to also include additional insulin formulations and dosage forms, such as fixed ratio mixes and concentrated insulin, at the same copay as Plan-Selected Model Drugs for one-month's-supply, in the deductible, initial coverage, and coverage gap phases of the benefit.

Part D sponsors wishing to participate in the Model must apply annually and may make changes to their supplemental benefits and formularies annually, in alignment with Part D and Model parameters.

Part D bid pricing tool submissions for participants must reflect the enhanced coverage for Model insulins as a supplemental benefit.

Within this Model, CMS is maintaining all current Part D formulary, tier, and utilization management requirements, except where waived for purposes of testing this Model. In addition, mid-year formulary changes to Model drugs (i.e., formulary additions, requests for utilization management updates, etc.) will be reviewed in accordance with existing Part D requirements. Model-participating PBPs must include a supplemental benefit that has a maximum copay of $35 per one month supply in the deductible, initial coverage, and the coverage gap phases[3] for at least one vial and one pen dosage form of each type of Model insulin that is a rapid-acting, short-acting, intermediate-acting, or long-acting insulin, where available. The supplemental benefit would be available for each Model insulin of these types that the participating PBP includes on the plan formulary.

Beyond this minimum Model requirement, Part D sponsors will choose the level of supplemental benefits to offer in the coverage gap for other Model insulins that are not required to be included on the formulary under this Model (i.e., that are not rapid-acting, short-acting, intermediate-acting, or long-acting), such as concentrated (e.g., U-500) and fixed ratio mixtures (e.g., 70/30), when labeled by a pharmaceutical manufacturer participating in the Model. While CMS strongly encourages Part D sponsors to follow the same coverage rules for all Model insulins offered on formulary (i.e., maintaining a maximum $35 copay per one month's supply in the deductible through coverage gap), Part D sponsors may choose the level of supplemental benefits, if any, to offer for other Model insulins.

Part D sponsors may also have to include non-Model insulins for purposes of CMS formulary requirements, depending on Model-participating manufacturers. In all scenarios, Part D formulary requirements must still be met and Part D sponsors must provide formulary exceptions where applicable at the approved cost sharing for the designated formulary exceptions tier(s). Therefore, if an enrollee is granted access to a non-formulary insulin through the formulary exceptions process, Part D sponsors are not required to offer the Model cost sharing. Part D sponsors are not required to offer a tiering exception to the copay for Plan-Selected Model Drugs for one month's-supply for any Model insulin or non-Model insulin.

For CY 2022, Model-participating Part D sponsors must offer a cost-sharing no greater than their maximum copay (whether that is $35 or lower) at all pharmacy types (preferred and non-preferred) and locations (retail and mail) for at least one vial and one pen dosage form of each type of Model insulin, where available, as specified in the participating PBP formulary. A Part D sponsor may choose to further enhance its benefit with a lower amount than $35 dollars, as this amount serves as a maximum for Model-participating PBPs. PBPs may choose to offer additional supplemental benefits to lower costs for beneficiaries, as allowed today, including in the deductible or initial coverage phases. For example, under current law and regulations, Part D sponsors may offer lower cost sharing at preferred pharmacies for Plan-Selected Model

[3] Please note that the Model does not test any changes to coverage or cost sharing in the catastrophic coverage portion of the Part D benefit, and the existing regulations at 42 CFR 423.104(d)(5) continue to apply.

Drugs.[4] To the extent that a PBP offers additional supplemental benefits as described in this paragraph, the lower cost sharing offered must be the same in all three phases (e.g., $20 in the deductible, initial coverage, and coverage gap phases). Additionally, if the remaining liability after the 70 percent manufacturer coverage gap discount is applied is less than $35, the beneficiary's liability would be the lower remainder.

As noted above, Part D sponsors are not required to grant a tiering exception to offer coverage at the Model-specific supplemental copay for any drug for which the PBP does not offer supplemental benefits under this Model, irrespective of whether the drug for which a tiering exception is being sought meets the definition of a Model drug.

CMS intends to make information on Model-participating PBPs readily available to all beneficiaries on Medicare Plan Finder, through open enrollment communications, and by all other means that CMS deems necessary for beneficiaries to be able to enroll in participating plans. CMS will provide additional information on this in the coming months.

Optional First Risk Corridor Threshold[5]: Part D sponsors have the option to opt-in, by indicating in the application, to be eligible for a 2.5, instead of 5, percent first threshold for the risk corridor. If the Part D sponsor prospectively opts in, CMS will apply a narrowed first risk corridor threshold, where a participating PBP has a statistically-significantly greater number of insulin-dependent diabetics, relative to other similar PBP types (standalone PDP, MA-PD, C-SNP, I-SNP), on at least one Model insulin. The statistical significance threshold will be defined as the PBP's proportion of enrollees with at least one fill of any Model insulin [proportion = (number of enrollees with at least one PDE of any Model insulin in the PBP) / (number of enrollees as of December of the plan year)] within the Model Year being at least one standard deviation above the Part D program average for that PBP type across all Model-eligible enhanced alternative PBPs for all Model insulins [proportion = (number of enrollees with at least one PDE of any Model insulin in any eligible enhanced alternative plan of a similar type) / (number of enrollees as of December of the plan year in any eligible enhanced alternative plan of a similar type)].

For those Model-participating PBPs that meet the one standard deviation or greater proportion of insulin-dependent diabetics on Model insulins, the first risk corridor threshold will begin at +/- 2.5 percent of the target amount instead of the 5 percent under current law today. All risk percentages between CMS and Part D sponsors – namely 50 percent risk for both CMS and Part

[4] Consistent with Chapter 5, Section 60.1 of the Medicare Prescription Drug Benefit Manual, Part D sponsors participating in the Part D Senior Savings Model must ensure that their enrollees have adequate access to covered Part D drugs (including Model drugs) dispensed at out-of-network pharmacies when needed. When determining the cost of the Model insulin the Part D sponsor is required to provide Model cost sharing consistent with the OON benefit structure submitted and approved in the PBP.

[5] In the event a PBP is in the Part D Payment Modernization (PDM) Model as well as the PDSS Model, during settlement, if a PBP would receive performance-based savings for the PDM Model, CMS will apply a standard adjustment factor to federal reinsurance savings to account for participation in both Models, as deemed necessary by CMS. For more details, please see the CY2022 Part D Payment Modernization RFA: https://innovation.cms.gov/media/document/partd-payment-modernization-cy22rfa.

D sponsors in between the first and second threshold and 80 percent CMS risk and 20 percent Part D sponsor risk beyond the second risk corridor threshold of 10 percent - remain the same.

CMS will calculate which participating PBPs will receive a narrower first threshold risk corridor in the months following a completed plan year, with the aim to make those results available to participating Part D sponsors in July following a plan year. This policy will apply for the first two years of the Model (CY 2021 and CY 2022).

Part D Rewards and Incentives (RI)

CMS is testing the impact of Model-participating Part D sponsors offering Part D RI that, in connection with Model-specific medication use, focus on promoting improved health, medication adherence, and the efficient use of health care resources. All proposed Part D RI Programs need to be designed to encourage enrollees in participating enhanced alternative PBPs to use Part D covered medications in ways that lead to improvement in at least one of these three areas (i.e., health outcomes, medication adherence, and the efficient use of health care resources). Part D plan sponsors should include any Part D RI Programs in their application for approval by CMS. Costs associated with approved Part D RI Programs would be included in the bid submission as a non-benefit expense as part of the plan's program description for applicable PBPs.

CMS has developed the following guidance to assist plans in developing their proposed Part D RI programs for this Model and Part D sponsors may target members with pre-diabetes and diabetes as defined in 42 CFR § 410.18(a). Part D sponsors may propose Part D RI Programs based on the guidelines below.

Permissible Part D RI Program Designs Generally

1. Part D RI Programs may be designed to target enrollees with pre-diabetes or diabetes who would benefit from participating in a disease state management programs specific for pre-diabetes or diabetes;

2. Part D RI Programs that provide rewards and incentives for participating in plan sponsor medication therapy management (MTM) programs that include a focus on a pre-diabetes or diabetes;

3. Part D RI Programs that provide rewards and incentives for enrollees with pre-diabetes or diabetes who participate in the receipt of preventive health services, such as receiving Part D covered vaccines; and

4. Part D RI Programs that enable enrollees with pre-diabetes or diabetes 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). There is an annual $600 cap per enrollee in the aggregate for all rewards, incentives, debit cards, and gift cards provided under the Model in each PBP (including, as applicable and discussed in more detail below, Part C and Part D RI offered in PBPs that are also participating in the Value-Based Insurance Design and/or Part D Payment Modernization Model).[6]

5. The maximum number and frequency of the rewards and incentives that may be obtained by an eligible enrollee per year.

6. 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:

- 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. Notwithstanding the limited scope of any potential fraud and abuse waivers of this Model, 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 money penalty prohibiting inducements to beneficiaries.
- Part D RI Programs are prohibited from providing rewards or incentives in the form of cash, cash equivalents, 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.

[6] The $600 cap applies cumulatively to all rewards and incentives offered under any of the three models in a single PBP. For example, an MA-PD that participates in more than one of the three models may offer an RI Program under each model, subject to the rules outlined in this section of the RFA, but the combined value of all rewards provided to an enrollee in the PBP under all the model RI programs must be equal to or less than $600. A Part C reward program offered under 42 CFR § 422.134 in the same PBP but not under the Model is not included when aggregating the rewards and incentives that are subject to the cap. The $600 cap is applied at the PBP level.

- 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. However, 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.

Requirements for PDPs and/or MA-PDs offering Part D RI under the Part D Payment Modernization (PDM) and/or VBID Model in addition to the PDSS Model

For CY 2022, multiple Part D RI programs are permitted to be offered in a single PBP under each of the PDM, PDSS, and VBID Models. This means that one PBP might include Part D RI Programs offered under up to three different Models. However, an underlying principle for the requirements for how a single PBP may offer RI Programs under more than one model is avoidance of overlap and duplication for an enrollee. PDPs and MA-PDs participating in either the PDM Model and/or the VBID Model, and proposing to offer Part D RI in a PBP that is in this Model, must comply with the requirements above in this Section 2.2 and the following:

- In no event may a participating plan offer a reward to an individual enrollee for completing the same activity under more than one RI Program; and

- An aggregate $600 cap, per enrollee per year, applies to all RI Programs offered across models – both Part D RI programs and Part C RI programs. For example, if an enrollee has earned a cumulative $600 in 2022 under a Part D RI Program offered under the PDM Model and a Part C RI Program offered under the VBID Model, the enrollee may not receive any rewards for participating in a Part D RI Program offered under the PDSS Model that year.

As part of monitoring PDSS Model participation, CMS will require participating Part D sponsors that have Part D RI Programs to report to CMS the form and manner of any Part D RI Program it offers. Specifically, Part D sponsors will be required to report: the number of enrollees targeted; the activities that must be completed to receive a reward; the number of enrollees that received the reward or incentive, including trends over time; and any evaluations of the effectiveness of such programs. If CMS determines that a Part D RI Program is not in compliance with the Model, CMS may impose sanctions or civil monetary penalties on the Part D sponsor in accordance with 42 CFR 422.723 or 423.752.

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. As part of the application process, CMS may offer guidance on what may or may not be acceptable in a proposal. The Part D RI program must be included in the participating plan's bid as a non-benefit expense. CMS, in its sole discretion, reserves the right to accept or reject any Part D RI program proposal.

Plan Eligibility: The Model is voluntary for eligible Part D sponsors nationally through their enhanced alternative PBPs offered either as standalone prescription drug plans (PDPs) or through Medicare Advantage coordinated care plans (i.e., HMO & PPO plans) that offer prescription drug coverage (MA-PDs). SNPs, with the exception of dual eligible special needs plans (D-SNPs), may participate (i.e., chronic condition and institutional special needs plans, – C-SNPs and I-SNPs – may participate).

Medicare Medical Savings Account, Private fee-for-service plans, all employer/union group waiver plans (EGWPs), section 1876 cost contract plans, section 1833 health care prepayment plans, PACE organizations, Medicare-Medicaid plans, and religious fraternal benefit plans are **not eligible** to participate in this Model.

Geographic Scope: The Model will be open to eligible organizations nationally, across all states and territories. Part D sponsors may choose which PBPs participate and are not required to apply in all regions in which it operates or with all PBPs.

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 applicable agreement with the Model participant.

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 beneficiary access to Model drugs, beneficiary enrollment in Model-participating PBPs, and any potential impacts on affordability and adherence due to the Model. Descriptions of some dimensions CMS intends to monitor through the Model are below:

- **Plan participant enrollment:** year-over-year trend differences in enrollment, including from non-enhanced PBPs and non-participating PBPs to Model PBPs. CMS will monitor this to see the extent that beneficiaries are taking up plans that offer an improved benefit around Model drugs.
- **Prescription drug list price**: for Model drugs, CMS will assess the extent to which list prices change. Of note, while this trend will be monitored and reviewed, confirming causation will not be a goal of this monitoring.

- **Direct and indirect remuneration and prescription drug net price**: CMS will examine the difference between the negotiated price and the net price of Model drugs, which reflects the cost of the Part D drug after manufacturer rebates and discounts, and other price concessions.
- **Premiums:** CMS will monitor premium trends, including basic premium and supplemental premiums, for participating vs. non-participating PBPs. CMS will also monitor changes to the actual premium paid by beneficiaries, especially in MA-PDs where a significant number of Medicare Advantage Organizations (MAOs) buy down the Part D premium to $0.
- **Beneficiary experience and drug access:** CMS will closely monitor the impact of the Model on beneficiaries. This will include, but not necessarily be limited to, formulary changes over time, and beneficiary access and satisfaction with Part D, including beneficiary questions or complaints through 1-800-MEDICARE or the Medicare.gov website.
- **Additional unintended consequences**: where applicable, CMS will monitor for any unexpected trends related to Part D costs, beneficiary access to and affordability of prescription drugs, beneficiary premiums, and beneficiary prescription drug appeals and grievances.

3.1 Enrollee Protections and Oversight

CMS will conduct regular monitoring to review Model participant compliance with the terms of the Model. 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. As noted above, this will include, but not necessarily be limited to, observing existing metrics of beneficiary access, outcomes, and satisfaction, and monitoring of increased beneficiary questions or complaints through 1-800-MEDICARE or the 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. Moreover, CMS will continue to work with the Medicare Beneficiary Ombudsman to coordinate a timely response to any Model-related beneficiary complaints, grievances, or requests for information.

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.

4. Evaluation

CMS will use an independent contractor to conduct an evaluation of the Model, which will examine the Model's implementation and assess the Model's impact on Medicare spending and

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, 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

Through this RFA, CMS is soliciting applications from eligible Part D sponsors to participate in the Model. The application process and selection for the Model is non-competitive. A Part D sponsor's participation in the Model is contingent upon its executing an approved contract to participate in the Part D program for CY 2022.

Part D sponsor Model applicants are required at the time of application to specify the PBPs to be included in the Model. As part of the application process, Part D sponsor applicants will be required to provide the parent organization information, including Part D sponsor contract number, PBP number(s), as well as names, titles, and contact information.

Part D sponsor applicants will attest that by applying, they agree to be part of the Model for the specific PBP(s) and region(s) applied for. PBPs approved to participate will need to note in the Health Plan Management System (HPMS) their participation in the Model. Model participation terms will be provided in a contract addendum to the Model participant's agreement with CMS to participate in Part D.

Part D sponsor Model applicants will submit to CMS, by 11:59 p.m. PDT on April 12, 2021, the proposed contract(s), PBP(s), and segments included in the Model via instructions found on the Model's website. Part D sponsor Model applicants will also submit: the name, strength, and dosage form of each Model insulin the Part D sponsor will offer at a maximum of $35 copay for a one-month's supply and the specific enrollee cost-sharing for each such Model insulin via a supplemental file available on the Model's website. Part D sponsors that are proposing to offer Part D RI must describe their RI programs in the application. Part D sponsors that wish to opt-in to be eligible for the optional narrower first risk corridor threshold must indicate that in the application.

CMS will confirm eligibility for the contracts and PBP(s) that Part D sponsors submit. Once confirmed, Part D sponsors will indicate their intended participation in the Model in HPMS by 11:59 p.m. PDT on June 7, 2021. In addition, as part of the Part D bid, Part D sponsor Model applicants will submit a supplemental file (uploaded through the formulary submission module) that contains the Model insulins and associated PBP cohort number for those Model insulins offered by the Part D sponsor by 11:59am EDT on June 11, 2021.

CMS will formally obligate participants to the terms of the Model for CY 2022 via a Model-specific supplemental contract addendum to their CY 2022 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 2021, 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; and
- Requirements for participation in CMS monitoring and evaluation activities.

Any Fraud and Abuse Waivers would be issued separately.

5.1 Model-specific Part D Guidance

CMS is providing guidance for Model applicants, and participants, that serves to augment existing CMS guidance for the purposes of the Model test. Model guidance includes, but is not limited to, the following:

PDE Submission

- **EA supplemental benefits in the coverage gap for Model insulins:** In order to facilitate the application of EA supplemental benefits after the gap discount, Model participants will report supplemental benefits provided in the coverage gap for Model insulins as if the supplemental benefits were other health insurance. As such, for costs in the coverage gap phase related to Model drugs, Part D sponsor participants will report supplemental benefits in the "patient liability reduction due to other payer" (PLRO) amount field on the PDE.
- **EA supplemental benefits outside of the coverage gap for Model insulins:** Model participants must continue to report applicable supplemental coverage for Model insulins in the "non-covered plan paid" (NPP) amount field on the PDE.
- **Low income cost-sharing (LICS) subsidy for Model insulins:** For calculating LICS, Model-participating plans should use the non-Model cost sharing of the formulary tier that the Model insulin is on, **not** the Model-specific copay for chosen Model insulins. For example, if a Model insulin is on a preferred brand tier with a $47 copay, a Model-participating plan should use the $47 copay to calculate LICS for a low-income subsidy eligible beneficiary and **not** the Model-specific copay.
- Please note that additional information on PDE submission for the Model may be found in an HPMS memo issued on May 21, 2020 located on the Model website.

5.2 Model Timeline

A summary of the Model's timeline is provided below:

Date	Milestone
January 14, 2021	CMS releases 2021 RFA for Pharmaceutical Manufacturers
January 27, 2021	Deadline for pharmaceutical manufacturers to apply (at 11:59 pm ET)
March 11, 2021	CMS confirms pharmaceutical manufacturer participation by publicly making list of CY 2022 participating manufacturers available via Model website, and releases RFA for Part D Sponsors
April 12, 2021	Deadline for Part D sponsors to apply (at 11:59 pm ET)
June 7, 2021	Part D bid deadline for CY 2022. Part D sponsor's bid reflects its intended participation in the Model
September 2021	CY 2022 Model contract addendum executed
January 1, 2022	Plan year begins

5.3 Withdrawal of Application

Part D sponsor applicant organizations seeking to withdraw an entire application or modify the scope of a pending application prior to the June bid deadline should submit a written request on the Part D sponsor's letterhead that is signed by the primary point of contact named in the application submission. To submit a withdrawal request, Part D sponsor Model applicants must send the request in a PDF format by email to PartDSavingsModel@cms.hhs.gov. The following information must be included in the letter:

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

5.4 Amendment of RFA

CMS may modify the terms of the Model 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.

Questions regarding the Model or application process may be sent by email to PartDSavingsModel@cms.hhs.gov. While CMS will not attribute any question to its author, CMS may publicly share responses to questions on the CMS Innovation Center website to ensure that all applicants have access to clarifying information regarding the Model and the application process.