Centers for Medicare & Medicaid Services

Center for Medicare & Medicaid Innovation

Part D Senior Savings Model

CY 2021 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. 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, beginning 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 will have the option to enroll in PDPs 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 30-days'-supply, that applies in the deductible, initial coverage, and coverage gap phases, for a broad set of Model insulins.

Current State and Model

Today, 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

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.

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 has 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 are higher relative to the initial coverage phase and beneficiaries have 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 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 would 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 plans will begin January 1, 2021, and for five plan years, CMMI will evaluate potential improvements to medication adherence 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 predictable, standard $35 copay for insulin.

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 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; and 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 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).

1.4 Medicare Program and Payment Waivers

In support of this Model, the Department intends to waive certain requirements under Title XVIII of the Act and its implementing regulations for purposes of testing the Model. No waivers of any kind are being issued in this document, which merely describes the waivers contemplated at this time for the Model. Programmatic waivers under consideration are 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 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 only for Model-participating PBPs with a statistically-significant (i.e., one standard deviation) greater number of insulin-dependent enrollees relative to all Model-eligible enhanced alternative PBPs of a similar plan type – PDPs, MA-PDs, C-SNPs, and I-SNPs - to be 2.5 percent instead of 5 percent;
- 42 C.F.R. § 423.329(d)(1) to the extent necessary to have the calculation of the low income cost-sharing subsidy on Model drugs for low-income subsidy eligible beneficiaries to be based on the non-Model cost sharing of the formulary tier that the Model drug is on and not the non-low income cost-sharing under the Model for the Model drugs (i.e. maximum of $35);
- 42 C.F.R. §423.578(a) to the extent necessary to permit Model-participating Part D sponsors to exclude from their tiering exceptions process any requests to apply Model cost sharing (that is $35 copay for a 30-days' supply) for any Model insulin or non-Model insulin;
- 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 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;
- 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, 2021; 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 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, if any, would be set forth in separately issued documentation. 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. Any such waiver would apply solely to the Model and could differ in scope or design from waivers granted for other programs or models.

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 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 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

Today, 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, 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, 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 under current law 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. 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 (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

For the 2021 plan year, which begins on January 1, 2021, CMS will test a voluntary Model for Part D sponsors, pharmaceutical manufacturers, and beneficiaries in all states and territories. 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 selected Model insulins, 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 and the National Drug Codes (NDCs) that Part D sponsors may reference for the list of insulins and other combination drugs that include insulin included in the Model.

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 30-days' 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, such as fixed ratio mixes and concentrated insulin, at the same $35 copay for 30-days'-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. Future bidding guidance will be released for participants prior to the 2021 bid deadline from the CMS Office of the Actuary.

CMS is maintaining all current Part D formulary, tier, and utilization management requirements, except where waived for purposes of testing this Model. Model-participating PBPs must include a supplemental benefit that has a maximum copay of $35 per 30-day supply in the deductible, initial coverage, and the coverage gap phases 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 30-days' 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. Part D sponsors are not required to offer a tiering exception to $35 for 30-days'-supply for any Model insulin or non-Model insulin.

For CY 2021, 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. To the extent that a PBP has a lower cost, it 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 $35 per 30-days' supply for any drug for which the PBP does not offer supplemental benefits at a $35 copay 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: 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 (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 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 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. Part D sponsors participating in any other CMMI Model that tests Part D RI, including the Enhanced Medication Therapy Management Model, Value-Based Insurance Design (VBID) Model, or the Part D Payment Modernization (PDM) Model, may only offer Part D RI under one model design.

Permissible Part D RI Program Designs Generally

1. Part D RI Programs may be designed to target enrollees with pre-diabetes or diabetes that participate 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 review of all of a beneficiary's medications and 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 preventive health services, such as receiving Part D covered vaccines; and

4. Part D RI Programs that allow enrollees with pre-diabetes or diabetes to engage and better understand their Part D plan benefit, costs, and clinically-appropriate coverage alternatives, including biosimilars, generics, and authorized generics.

While nothing prohibits Part D sponsors from engaging more broadly with beneficiaries, Part D RI programs associated with this Model must be limited to the above defined activities.

Impermissible Part D RI Programs

1. 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 to 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, or manufacturer-supplied educational materials. Further, Part D sponsors may not, in connection with the Part D RI programs under this Model, 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, or pharmacy-supplied education materials.

Requirements for Part D RI Programs

1. Part D RI Programs must be complete by the end of a plan year. Part D RI Programs may not be designed around enrollees carrying over rewards and incentives from one contract year to the next. This does not mean that any reward and incentive provided to a beneficiary expires at the end of a plan year. This only means that a reward and incentive must be provided in conjunction with permissible activities within a plan year.

2. 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, or other CMS-approved health-related activity or service for which they offer rewards and incentives.

Part D sponsors may propose a maximum of $600 in Part D RI annually through this Model.

3. 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.

4. Part D RI Programs are prohibited from providing rewards or incentives in the form of cash, cash equivalents, or other monetary rebates.

5. 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. 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.

7. 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.

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 the Model's monitoring and evaluation, participating Part D sponsors that offer Part D RI Programs must submit to CMS the form and manner of 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 who 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 monetary penalties on the Part D sponsor.

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 plans that offer prescription drug coverage (MA-PDs). Coordinated care plans, **excluding** 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).

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, PACE organizations, Medicare-Medicaid plans, and religious fraternal benefit plans (local coordinated care plans and private fee-for-service plans) are **not eligible** to participate in the 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

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, 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 2021.

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, applicants will be required to provide the parent organization information, including Part D sponsor contract number, plan benefit package number(s), as well as names, titles, and contact information.

Applicants will attest that by applying, they agree to be part of the Model for the specific plan benefit package(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.

CMS is requesting letters of intent from interested Part D sponsors by 11:59 p.m. EDT on April 10, 2020. The letter of intent should indicate the following: the proposed contract(s), PBP(s), and segments to be included. To the extent a Part D sponsor is still determining the contracts and PBPs to be included, CMS is requesting the state(s) that the Part D sponsor is intending to participate in. The letter of intent is non-binding. Information on submitting the letter of intent will be available on the Model website.

Model applicants will submit to CMS, by 11:59 p.m. EDT on May 1, 2020, the proposed contract(s), PBP(s), and segments included in the Model via instructions found on the Model's website. 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 copayment for a 30-days' 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 the HPMS

and those Part D sponsors proposing to offer Part D RI will include in the MRx Notes section of their Part D PBP the following language: "The PBP will implement a Part D RI program in accordance with any final Application Proposal approved by CMMI." by 11:59 p.m. PDT on June 1, 2020. In addition, during the Part D bid and benefit review, Model applicants will submit a supplemental file that contains the Model insulins and associated cost sharing for those Model insulins offered by the Part D sponsor.

CMS will formally obligate participants to the terms of the Model for CY 2021 via a Model-specific supplemental contract addendum to their CY 2021 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; 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 CY 2021 guidance for Model applicants, and participants, that serves to augment existing CMS guidance for the purposes of the Model test. CMS is providing guidance on Prescription Drug Event (PDE) submission and PBP software submission under the Model for CY 2021.

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, 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 $35 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 $35 copay.

PBP Submission

Instructions to participating Part D sponsors when submitting its PBP:

- If the intent is to not offer additional gap coverage for drugs other than the Model insulins, indicate in the PBP that you are NOT offering additional gap coverage in the PBP.
- If the intent is to offer additional gap coverage for drugs other than the Model insulins, indicate in the PBP that you are offering additional gap coverage. When designating which specific tier(s) that the additional gap coverage applies, only select those tiers for which additional gap coverage will be offered for non-Model drugs. Do NOT include the tier(s) for which the additional gap coverage only applies to the Model insulins.

5.2 Model Timeline

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

Date	Milestone
March 11, 2020	CMS announces Model and releases RFAs for Pharmaceutical Manufacturers and Part D Sponsors
March 18, 2020	Deadline for pharmaceutical manufacturers to apply (at 11:59 pm EDT)
March 20, 2020	CMS confirms pharmaceutical manufacturer participation by publicly making list of participating manufacturers available via Model website
April 10, 2020	Initial Letter of Intent Submission for Part D Sponsors (at 11:59 pm EDT)
May 1, 2020	Deadline for Part D sponsors to apply (at 11:59 pm EDT)
June 1, 2020	Part D bid deadline for CY 2021. Part D sponsor's bid reflects its intended participation in the Model
September 2020	Model contract addendum executed
January 1, 2021	Model begins

5.3 Withdrawal of Application

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, 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.