Centers for Medicare & Medicaid Services

Center for Medicare & Medicaid Innovation

Part D Senior Savings Model

Request for Applications for

Pharmaceutical Manufacturers

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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) is for pharmaceutical manufacturers that market applicable drugs and outlines Model design elements, Model eligibility criteria, and additional Model details for manufacturers 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. 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 results 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 manufacturers will begin upon execution of the Model contract addendum. 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.

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-day's 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 and Manufacturer Eligibility

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.

Pharmaceutical Manufacturer Eligibility: CMS is testing this Model for applicable drugs that are, or contain a drug classified as insulin in the 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. Pharmaceutical manufacturers that currently have a Medicare Coverage Gap Discount Program Agreement and label and market an applicable drug that is, or contains, a drug classified as insulin in AHFS Drug Information or the DRUGDEX Information System compendia are eligible to apply.

Inclusion of All Applicable Drugs that are, or contain, insulin as Model drugs: To participate in the Model, the pharmaceutical manufacturer must agree to include all marketed drugs that meet the definition of covered Part D drug set forth in section 1860D-2(e) of the Act labeled by it or a subsidiary that is, or contains, a drug classified as insulin in the AHFS Drug Information or

the DRUGDEX Information System compendia. Supplies associated with the injection of insulin are not included in the Model. While pharmaceutical manufacturers that participate will include all applicable drugs, as defined in section 1860D-14A(g), that are, or contain, insulin as Model drugs, Part D sponsors that participate will choose from the total set of Model drugs in setting plan formularies that meet CMS formulary requirements as well as Model requirements, as outlined below.

Part D Sponsor Requirements: Part D sponsors' participating PBPs are required to offer at least one vial dosage form and one pen dosage form of each insulin type, defined as rapid-acting, short-acting, intermediate-acting, and long-acting, at a $35 copay for 30-days' supply in the deductible, initial coverage, and coverage gap phases, where there is (i) a participating manufacturer for that type of insulin; and (ii) a Part D sponsors' participating PBP includes that Model drug on formulary. Part D sponsors have the option to offer supplemental benefits for additional Model drugs beyond this minimum and CMS encourages Part D sponsors and participating pharmaceutical manufacturers to partner to offer beneficiaries plan choices that include a broad a set of formulary insulins and insulin-containing combination drugs. Please refer to the RFA for Part D sponsors for all Model requirements for Part D sponsors.

Applicability to New-to-Market Products: The contract addendum will apply to all currently marketed NDCs of the Manufacturer's Model drugs and any additional NDCs that are Model drugs and become available during a contract year.

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

5.1 Application Process and Selection

Through this RFA, CMS is soliciting applications from pharmaceutical manufacturers that currently have a Medicare Coverage Gap Discount Program Agreement and label and market an applicable drug that is, or contains, a drug classified as insulin in the AHFS Drug Information or the DRUGDEX Information System compendia.

Manufacturers that participate in the Model will execute an addendum to the current Manufacturer Coverage Gap Discount Program Agreement. The contract addendum is provided separately on the Model website. The addendum will require pharmaceutical manufacturers to contribute the current law manufacturer discounted price in the coverage gap for enrollees in Model-participating PBPs that offer supplemental benefits for the manufacturer's Model insulins in a Model year based on the negotiated price for the Model Drug without regard to any Part D supplemental benefits that are available.

The application process and selection for the Model are non-competitive and open to all pharmaceutical manufacturers that manufacture and label applicable covered Part D drugs that are, or contain, insulin, as classified in the AHFS Drug Information or the DRUGDEX Information System compendia. While CMS expects to have an annual RFA for each year of the Model, eligible manufacturers will continue to participate each year per the terms of the contract addendum, barring termination of that addendum by the stated dates.

CMS will formally obligate pharmaceutical manufacturers to the terms of the Model via a Model-specific contract addendum to the Manufacturer Agreement.

Pharmaceutical manufacturers must submit to CMS, by 11:59 pm EDT March 18, 2020, an executed contract addendum to the Manufacturer Agreement. The executed contract addendum will include an Appendix of all NDCs for currently marketed Model insulins by each of the manufacturer's labeler codes.

CMS will approve applications and execute the contract addendum for each approved applicant the week of March 16, 2020. The list of participating manufacturers and NDCs will be available on the Model website for Part D sponsors.

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
January 1, 2021	Model begins

5.3 Withdrawal of Application

Prior to 11:59 pm EDT March 18, 2020, a pharmaceutical manufacturer that submitted an executed contract addendum to the Manufacturer Agreement may withdraw from participating by submitting a written request on the organization's letterhead that is signed by the executor of the contract addendum. To submit a withdrawal request, applicants must send the request in a PDF format by email to PartDSavingsModel@cms.hhs.gov.

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. Please refer to the contract addendum for the full terms of 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.