



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

**Part D Senior Savings Model  
2021 Request for Applications for  
Pharmaceutical Manufacturers for Plan Year 2022**

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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 additional 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.<sup>1</sup> 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 to join the model in 2021 and support an enhanced alternative benefit design provided by Model-participating Part D sponsors starting with the 2022 plan year. 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,

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<sup>1</sup> “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; or (iii) is provided through an exception or appeal.

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*

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 manufacturers begins on execution of the Model contract addendum and modifies the supplemental coverage options for the manufacturer’s Model Drugs in the subsequent plan years of the Model. 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 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 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; 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), 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 new manufacturer applicants that join the Model 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 manufacturer applicants that join the Model and Part D sponsor participants in the Model. Programmatic waivers under consideration are the following:

### *For Manufacturer applicants that join the Model*

- 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;
- 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.

*For Part D sponsor participants in the Model*

- 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 standalone PDPs that are not participating in the Model when the impact is directly attributable to participation in the Model; and
- 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.

### 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 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 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. 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 Outside the Model: Examples*

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 ( $25\% \times \$500 = \$125$ ). The Part D sponsor's liability is the remaining 5 percent ( $5\% \times \$500 = \$25$ ). 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 ( $70\% \times \$35 = \$24.50$ ). 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, under current law, any increase in Part D sponsor liability on supplemental benefits would increase plan supplemental premiums, a limited number of Part D sponsors outside the Model 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. This Model tests whether increasing access, affordability, and adherence to Model insulins 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

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 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 its Plan Selected Model Drugs 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 maximum copay of \$35 for one-month's 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 sponsor's 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 additional information from Model participants, particularly in response to high levels of complaints or other indicators of poor performance. CMS will closely monitor Model implementation to ensure that 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.

CMS will formally obligate pharmaceutical manufacturers to the terms of the Model via a Model-Specific addendum to the current Manufacturer Coverage Gap Discount Program Agreement (hereinafter “Coverage Gap Agreement”). The contract addendum applicable to manufacturers seeking to join the Model in 2021 is provided separately on the Model website. Among other provisions, the addendum will require pharmaceutical manufacturers to reimburse all Applicable Discounts provided to Model-Participating Part D Sponsors for all Plan-Selected Model drugs 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.

Pharmaceutical manufacturers seeking to join the Model must submit to CMS, by 11:59 pm EDT January 27<sup>th</sup>, 2021, an executed contract addendum. 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 February 8<sup>th</sup>, 2021. 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
January 14, 2021	CMS releases 2021 RFA for Pharmaceutical Manufacturers
January 27, 2021	Deadline for pharmaceutical manufacturers to apply (at 11:59 pm EDT)
February 2021	CMS confirms pharmaceutical manufacturer participation by publicly making list of participating manufacturers available via Model website
March 2021	Deadline for Part D sponsors to apply (at 11:59 pm EDT)
June 7, 2021	Part D bid deadline for CY 2022. Part D sponsor’s bid reflects its intended participation in the Model
January 1, 2022	CY 2022 performance period of the Part D Senior Savings Model begins

## 5.3 Withdrawal of Application

Prior to 11:59 pm EDT February 5, 2021, a new pharmaceutical manufacturer applicant that submitted an executed contract addendum to the Coverage Gap Agreement for CY 2022 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](mailto: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](mailto: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.