ADDENDUM TO CONTRACT FOR THE OPERATION OF A VOLUNTARY MEDICARE PRESCRIPTION DRUG PLAN FOR PARTICIPATION IN THE PART D SENIOR SAVINGS MODEL
(the "Addendum")

The Centers for Medicare & Medicaid Services ("CMS") and <<CONTRACT NAME>> a Medicare Part D Prescription Drug Plan Sponsor ("Part D Sponsor") agree to amend the contract <<CONTRACT_ID>>, including all attachments, addenda, and amendments thereto, (the "Underlying Contract"), governing the Part D Sponsor's operation of a Voluntary Medicare Prescription Drug Plan pursuant to §§1860D-1 through 1860D-43 (with the exception of §§1860D-22(a) and 1860D-31) of the Social Security Act ("Act"), to include this addendum to provide for the Part D Sponsor's participation in the Part D Senior Savings Model (the "Model").

This voluntary Model, conducted pursuant to Section 1115A of the Act, is intended to exist for five plan years of the Part D Program, and commenced with plan year 2021. The purpose of this Model is to test a change to the Medicare Coverage Gap Discount Program to allow Part D sponsors, through eligible enhanced alternative plans, to offer a Part D benefit design that includes predictable, stable copays in the deductible, initial coverage, and coverage gap phases by offering supplemental benefits that apply, in the coverage gap, after manufacturers provide a discounted price for applicable drugs included in the Model without regard for the Special Rule for Supplemental Benefits.

The parties hereby amend the Underlying Contract by adding the following:

Article 1
Model Term and Part D Sponsor Participation

A. This Addendum becomes effective on the date it is signed by CMS ("Effective Date") and will remain in effect through December 31, 2022, unless sooner terminated in accordance with Articles 6 or 8 of this Addendum. This Addendum covers plan year 2022 for the Part D Senior Savings Model, which will start on January 1, 2022 ("Start Date"). If Part D Sponsor wishes to participate in the Model during a subsequent plan year, it must timely submit for CMS review a Model application for the relevant plan year in addition to its annual Part D bid submission and enter into a contract addendum for participation in the Model for that plan year.

B. Part D Sponsor may participate in the Model only with the eligible plan benefit packages (PBPs) providing Enhanced Alternative Coverage that are identified in the Approved Proposal (each a "Model PBP").

C. The following plan types and programs are not eligible plan benefit packages and may not participate in the Model: PBPs for dual-eligible special needs plans (D-SNPs); Private Fee-

For-Service (PFFS) Plans; Employer/Union Group Waiver Plans (EGWPs); cost plans offered under section 1876 of the Act; Health Care Prepayment Plans (HCCP) offered under section 1833 of the Act; Programs of All-Inclusive Care for the Elderly (PACE); Medicare-Medicaid Plans (MMP) and other demonstration plans; and Religious Fraternal Benefit (RFB) plans.

Article 2
Definitions

"Approved Proposal" means the Part D Sponsor's final approved application including, if applicable, any Part D RI Programs, allowing for the Part D Sponsor's participation in the Model in plan year 2022 and all corresponding bid submissions as finalized.

"Diabetes" has the meaning set forth in 42 CFR § 410.18(a).

"Enhanced Alternative Coverage" has the meaning set forth in 42 CFR § 423.100.

"Model Beneficiary" means an applicable beneficiary as defined in 42 CFR § 423.100 enrolled in a Model PBP.

"Model Guidance" refers to documentation provided by CMS outlining requirements related to participation in the Model, including guidance on Model monitoring and necessary data submissions, and guidance on marketing and other communications for Part D sponsors participating in the Model.

"Model Drug" means an applicable drug as defined in 42 CFR § 423.100 that is, or contains, a drug classified as insulin in American Hospital Formulary Service (AHFS) Drug Information or the DRUGDEX Information System compendia, and is marketed by and available from a Model-participating manufacturer. CMS lists Model Drugs on the Model website.

"Model PBP" stands for Model plan benefit package and has the meaning set forth in Section B of Article 1.

"**Model-Specific Supplemental Benefits"** means supplemental benefits that conform to the Model requirements in Section C of Article 3.

"PDP" stands for prescription drug plan and has the meaning set forth in 42 C.F.R. § 423.4.

"Part D RI Program" stands for Part D Rewards and Incentives Program and means a program, as identified in the Part D Sponsor's Approved Proposal, that offers certain rewards and incentives that are connected to the Part D Prescription Drug Benefit.

"Plan Selected Model Drug" means a Model Drug identified in the Part D Sponsor's Approved Proposal for which Part D Sponsor offers Model-Specific Supplemental Benefits.

"Pre-diabetes" has the meaning set forth in 42 CFR § 410.18(a).

"Special Rule for Supplemental Benefits" means § 1860D-14A(c)(2) of the Act.

"Targeted Enrollee" means a Medicare beneficiary who is enrolled in one of the Part D Sponsor's Model PBPs and who is targeted by the Part D Sponsor to receive rewards and incentives in the Part D Sponsor's RI program based on the Approved Proposal.

Article 3
Functions to be Performed by Part D Sponsor

A. Part D Bid and Benefit Package Submission and Review.

Part D Sponsor certifies that its annual benefit and bid submission for each Model PBP is consistent with the Approved Proposal (unless otherwise authorized in writing by CMS) and in accordance with all program and bid instructions issued by CMS for applicants to the Model.

B. Model Implementation Requirements.

1. Part D Sponsor shall comply with all applicable laws governing its operation and offering of qualified prescription drug coverage, except as specifically waived in writing in accordance with section 1115A of the Act.

2. Part D Sponsor shall implement the Model in each Model PBP on the Start Date and in accordance with the Approved Proposal and this Addendum, including without limitation Appendix 2.

3. Part D Sponsor shall:

   i. Carry out this Addendum in a manner that is consistent with the efficient and effective implementation of 42 C.F.R. Part 423 (as applicable) and Section 1115A of the Act;

   ii. Comply with the Model Guidance, including, without limitation, requirements regarding the timely submission of data to facilitate Model monitoring;

   iii. Not take any action that threatens the health or safety of an enrollee; and

iv. Ensure Part D Sponsor's participation in the Model does not result in lower quality of care or other adverse outcomes for enrollees.

C. Model-Specific Supplemental Benefits.

1. Part D Sponsor shall comply with all applicable laws, regulations, and guidance regarding formulary design, except as expressly modified by this Addendum.

2. For each Model PBP, Part D Sponsor shall furnish Model-Specific Supplemental Benefits for Plan Selected Model Drugs in accordance with the Approved Proposal and the following requirements:

    a. Copayment. Part D Sponsor's Part D benefit will specify a copayment of no more than thirty-five dollars ($35) for a month's supply of any Plan Selected Model Drug in the deductible, initial coverage, and coverage gap phases. If Part D Sponsor covers a Plan Selected Model Drug in larger increments than a month's supply, such as 2 or 3 month's supply, the copayment on such increment must be equal to or less than the multiple of the month's supply copayment (i.e., 2 times for 2 months and 3 times for 3 months) consistent with current CMS requirements.

    b. Drug Type. Plan Selected Model Drugs must include at least one Model Drug of each the following types of insulins: rapid-acting, short-acting, intermediate-acting, and long-acting.

    c. Dosage Form. Plan Selected Model Drugs must include both the vial dosage form and pen dosage form for all Plan Selected Model Drugs, unless a Plan Selected Model Drug is not manufactured in both dosage forms.

    d. Supply Duration. The Part D Sponsor shall determine a month's supply of any Plan Selected Model Drug in a manner consistent with how it determines month's supplies of other Part D drugs.

    e. Pharmacy Type. The Part D Sponsor shall provide Model-Specific Supplemental Benefits for Plan Selected Model Drugs without regard to pharmacy type. Part D Sponsor may continue to offer a lower copay for a Plan Selected Model Drug at preferred or mail-order pharmacies in accordance with Part D program guidelines.

3. Nothing in this section prevents a Part D Sponsor from offering supplemental benefits for Model Drugs that are not Plan Selected Model Drugs.

D. Part D Rewards and Incentives Programs.

1. Part D Sponsor shall implement any Part D RI Program under this Addendum only in the Model PBPs for which the Approved Proposal includes a Part D RI Program. Part D Sponsor shall implement any Part D RI Program on the Start Date and in a manner that is consistent with the Approved Proposal and this Addendum, including without limitation Appendix 2.

2. The methodologies and criteria used by the Part D Sponsor to implement any Part D RI Program must be specified in the Approved Proposal and able to be replicated by CMS, applied uniformly to all enrollees who meet the defined criteria, be evidence-based, and be expected to materially impact the health of the targeted population. The targeted population for the Part D RI Program must be limited to enrollees in a Model PBP with Diabetes or Pre-diabetes.

3. Part D Sponsor shall identify the Targeted Enrollees who met the eligibility criteria to receive rewards and incentives under the Part D RI Program based on the Part D Sponsor's Approved Proposal and information known to Part D Sponsor.

4. Part D Sponsor shall submit to CMS all targeting and engagement data used in the Part D RI Program (e.g., data regarding outreach to Targeted Enrollees) in a form, manner, and on the timeline specified by CMS in this Addendum or the Model Guidance.

5. Part D Rewards and Incentives are not benefits and may not be listed in the Evidence of Coverage or Annual Notice of Change (ANOC). In any marketing materials regarding Part D RI Programs, the Part D Sponsor shall include: (1) the intended goal of the reward and incentive program(s); (2) what must be done to receive the rewards and incentives; (3) the per unit value of the reward and incentive; (4) the total value that an enrollee can receive; and (5) how to ask questions or receive help on understanding the rewards and incentives program.

6. Because eligibility for a particular reward or incentive under any Part D RI Program is not assured or cannot be determined before a plan year for a specific enrollee or enrollees, the Part D Sponsor shall provide a disclaimer on all materials describing the reward, incentive, or Part D RI Program. Such disclaimer must clearly state that eligibility for the Part D reward or incentive under the Model is not assured and will be determined by the Part D Sponsor after enrollment based on relevant criteria (e.g., clinical diagnosis of Pre-diabetes or Diabetes, participation in a disease state management program).

D. Compliance with Model Guidance.

1. In addition to the requirements in the Underlying Contract and this Addendum, Part D Sponsor shall comply with any Model Guidance, including for monitoring, communication

and marketing, issued by CMS and available on the Model website at https://innovation.cms.gov/innovation-models/part-d-savings-model. Changes in the URL for the Model's dedicated website will be communicated to Part D Sponsor by CMS.

2. As applicable, Part D Sponsor shall submit any Model-related communications materials to CMS using the Health Plan Management System as specified by CMS.

3. In the event of a conflict between the marketing requirements in the Underlying Contract and the Model Guidance such that Part D Sponsor cannot comply with both, Part D Sponsor must comply with any Model Guidance.

E. Notice of Changes.

The Part D Sponsor shall not make any changes to the Approved Proposal, without prior, written CMS approval, except that Part D Sponsor may make formulary changes and provide notice (when required) in accordance with existing Part D requirements. In addition, the Part D Sponsor agrees to provide CMS written notice of any change in circumstances that would constitute a material change to a fact or representation made in Part D Sponsor's Approved Proposal, including not implementing a Part D RI Program or not providing Model-Specific Supplemental Benefits.

F. Release of Information.

1. Part D Sponsor shall obtain prior approval from CMS during the term of this Addendum and for six months thereafter for the publication or release of any press release, external report or statistical/analytical material or other similar material that references Part D Sponsor's participation in the Model. External reports and statistical/analytical material may include papers, articles, professional publications, speeches, and testimony. When reviewing these materials, CMS intends to disapprove only those materials containing material misstatements of fact or conclusions based on improper methodology or inaccurate data, or that are inconsistent with the implementation of the Model or other applicable laws, regulations, or CMS instructions. CMS will make reasonable efforts to complete its review expeditiously. Any material submitted to CMS for prior approval that is not disapproved in writing by CMS, or where CMS has requested additional time to review, within 30 calendar days after receipt by CMS will be deemed approved.
2. Part D Sponsor agrees to include the following statement on the first page of all external reports and statistical/analytical material that are subject to this Section: "The statements contained in this document are solely those of the authors and do not necessarily reflect the views or policies of CMS. The authors assume responsibility for the accuracy and completeness of the information contained in this document."

G. Non-Discrimination. Part D Sponsor shall not discriminate against enrollees in any Model PBP.

Article 4
Optional Narrowing of First Risk Corridor Threshold

A. Applicability of Article.

This Article 4 applies only if the Part D Sponsor's Approved Proposal indicates, at the PBP level, election of a narrowed first risk corridor threshold.

B. Optional Narrowed First Risk Corridor Threshold.

For a Model PBP for which the narrowed first risk corridor has been elected, if the Model PBP's aggregate proportion of insulin-dependent diabetic enrollees is one standard deviation or greater above the average for all Model-eligible enhanced PBPs of the Model PBP's plan type calculated as described in Section C of this Article 4, CMS will apply a narrowed risk corridor for that Model PBP. Under the narrowed risk corridor, the government will bear or retain 50 percent of the difference between 2.5 percent and 10 percent of the target amount, as defined in Section 1860D-15(e)(3)(B) the Act.

C. Determination of Eligibility for Narrowed First Risk Corridor Threshold.

All calculations determining the application of the optional narrowed first risk corridor threshold will be performed using the data available to CMS following reconciliation under 42 C.F.R. Part 423 for the plan year. CMS shall determine whether the narrowed first risk corridor applies to a Model PBP using the following methodology:

1. Determine average proportion of beneficiaries that utilize a Model Drug for each of the eligible model plan types. CMS will determine for each of the following plan types the average proportion of beneficiaries for that plan type that utilize a Model Drug: (i) Model-eligible standalone PDPs; (ii) Model-eligible MA-PDs, excluding Special Needs Plans (SNPs); (iii) Model-eligible Chronic Condition Special Needs Plans (C-SNPs); and (iv) Model- eligible Institutional Special Needs Plans (I-SNPs). For each of the types of plans above, CMS determines the number of enrollees in the plan type with at least one Prescription Drug Event (PDE) for any Model Drug in the plan year reported to CMS by June 30 following a plan year. CMS divides that number by the total number of enrollees in the eligible plan type as of December of the plan year. This will yield the proportion of beneficiaries that have at least one Model Drug PDE for the plan year in each plan type (i.e., eligible standalone PDPs, eligible MA-PDs (excluding SNPs), eligible C-SNPs, and eligible I-SNPs).

2. Calculate the standard deviation for each plan type (i.e., eligible standalone PDPs, eligible MA-PDs (excluding SNPs), eligible C-SNPs, and eligible I-SNPs).

3. Calculate the statistical significance threshold for each plan type by adding the standard deviation determined in step 2 of this Section C to the average proportion determined in step 1 of this Section C for each plan type. The statistical significance threshold will be calculated at two decimal places.

4. Calculate the proportion of enrollees in the Model PBP that used a Model Drug in the plan year. CMS determines the number of enrollees in the Model PBP with at least one PDE for a Model Drug in the plan year, as reported to CMS by June 30 following the plan year and divides this number by the Model PBP's total number of enrollees in the eligible plan type as of December of the plan year. The Model PBP's proportion will be calculated at two decimal places.

5. Determine eligibility for the narrowed first threshold risk corridor. For each Model PBP for which the narrowed first risk corridor has been elected, if the Model PBP's proportion, as calculated in step 4 of this Section C, is greater than or equal to the statistical significance threshold, as determined in step 3 of this Section C, CMS applies the narrowed risk corridor as described in Section D of this Article 4. Otherwise, CMS applies the risk corridors as specified in section 1860D-15(e) and 42 C.F.R. § 423.336.

D. Application of narrowed risk corridor for eligible Model PBPs.

For each Model PBP that meets the eligibility requirements for the narrowed risk corridor as described in Section C of this Article 4, CMS calculates the portion of total payments subject to risk consistent with 42 C.F.R. § 423.336, except that CMS substitutes 2.5 percent for 5 percent for purposes of 42 C.F.R. §423.336(a)(2)(ii)(A)(3). Except as specified in this Section D, all other Part D requirements with respect to the calculation and application of risk corridors apply.

Article 5
Additional Record Retention and Reporting Requirements

A. Record Maintenance and Access.

1. Part D Sponsor shall maintain records relating to the Model for 10 years. The Part D Sponsor shall provide access to such records in accordance with the record retention provisions of the Underlying Contract.

B. Data Reporting & Cooperation with Monitoring and Evaluation.

1. Part D Sponsor shall cooperate with CMS's efforts to evaluate the effectiveness of the Model and shall participate in all Model-related monitoring, auditing, evaluation, and

learning and diffusion activities. The obligation to cooperate in Model-related monitoring, auditing, and evaluation shall survive termination of the Part D Sponsor's participation in the Model.

2. The Part D Sponsor shall submit to CMS, in a form, manner, frequency, and by a deadline specified by CMS data to monitor the real-time impact of the Model and to perform the requisite Model evaluation. Part D Sponsor shall comply with any instructions regarding the collection and submission of data regarding the Part D Sponsor's participation in Model, including without limitation the data outlined in Appendix 2. CMS will make a reasonable effort to limit data submission from Part D Sponsors to data that is not readily available to CMS, such as any implementation of Part D RI Programs.

Article 6
Termination of Addendum or Model PBP Participation by CMS

A. CMS may terminate this Addendum or terminate one or more particular PBP(s) from the Model at any time, with or without advance notice, if:

1. CMS terminates the Model pursuant to Section 1115A(b)(3)(B) of the Act or otherwise;
2. CMS determines that Part D Sponsor or a particular PDP, MA-PD, or its subcontractor or downstream entity (as defined at 42 C.F.R. § 423.4):

   i. Has failed to comply with any term of this Addendum or documents incorporated herein;

   ii. Has carried out this Addendum in a manner that is inconsistent with the efficient and effective implementation of 42 C.F.R. Part 423 or Section 1115A of the Act;

   iii. Has failed to continually meet the applicable eligibility conditions, or does not have an exception to one or more eligibility conditions, of the Model;

   iv. Has failed to implement or fully comply with the terms of a corrective action plan or other intermediate sanction;

   v. Has taken an action that threatens the health or safety of an enrollee, or Part D Sponsor's participation in the Model is resulting in lower quality of care or any other adverse outcomes for enrollees;

   vi. Has submitted false data or made false representations, warranties, attestations or certifications in connection with any aspect of the Model;

vii. Is subject to sanctions or other enforcement or correction actions of an accrediting organization or federal, state, or local government agency;

viii. Is subject to investigation or action by HHS (including HHS-OIG and CMS) or the Department of Justice due to an allegation of fraud or significant misconduct, including being subject to the filing of a complaint, filing of a criminal charge, being subject to an indictment, or being named as a defendant in a False Claims Act qui tam matter in which the government has intervened or similar action;

ix. Assigned or purported to assign any of the rights or obligations under the Underlying Contract or this Addendum voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of CMS;

x. Experiences financial difficulties so severe that its ability to make necessary health services available is impaired to the point of posing an imminent and serious risk to the health of its enrollees, or otherwise fails to make services available to the extent that such a risk to health exists;

xi. Has committed any act that would be cause for termination of the Underlying Contract or imposition of any penalty or sanction thereunder, regardless of whether such termination, penalty or sanction is actually imposed by CMS; or

xii. Has engaged in prohibited discrimination against a Medicare beneficiary.

B. Prior to terminating the Addendum or a particular Model PBP's participation in the Model pursuant to this Article 6, CMS may afford the Part D Sponsor an opportunity to develop and implement a corrective action plan to correct deficiencies in accordance with the procedures of 42 C.F.R. Section 423.509(c)(1).

C. In addition to any sanction or penalty authorized under 42 C.F.R. 423.750, CMS may rescind or make inapplicable on a prospective basis one or more waivers provided to Part D Sponsor, or limit the benefits or Part D RI Programs that may be offered by Part D Sponsor if CMS determines that an event identified in Paragraph A.2 of this Article has occurred.

Article 7
Modifications of Addendum

A. This Addendum may be modified at any time by written mutual consent.

B. CMS may modify this Addendum without the consent of the Part D Sponsor for good cause or as necessary to comply with applicable federal or state law, regulatory requirements, or accreditation standards. To the extent practicable, CMS shall provide the Part D Sponsor with 30 calendar days advance written notice of any such unilateral amendment, which

notice shall specify the amendment's effective date. If the Part D Sponsor does not wish to be bound by the unilateral amendment, it may terminate this Addendum by providing CMS with 30 days advance written notice.

Article 8
Procedure upon Termination and Surviving Obligations

A. As the term of this Addendum is from the Start Date through the 2022 plan year, if Part D Sponsor does not wish for its Model PBPs to continue participating in the Model for the upcoming plan year, it must notify CMS in writing by the first Monday in June that precedes the start of the upcoming plan year.

B. If the Plan Sponsor does not wish to continue participation in the Model, the Part D Sponsor must notify enrollees in the Model PBP by including a notification in the ANOC for the PBP. Such notice must comply with Part D communications and marketing requirements, including without limitation any Model Guidance.

C. Part D Sponsor shall ensure timely transfer of any data or files to CMS necessary for monitoring, assessment, transition or close-out of Part D Sponsor's Model-related activities and shall comply with all other CMS-specified close-out procedures.

D. Termination of this Addendum by either party shall not affect the rights and obligations of the parties accrued prior to the effective date of the termination or expiration of this Addendum. The termination of this Addendum does not relieve either party of any claims against it that arise under this Addendum before the Addendum is terminated.

E. Upon any termination of this Addendum (other than pursuant to Article 6), Part D Sponsor shall continue to provide coverage for items and services consistent with applicable law and the Underlying Contract as if this Addendum had never been executed. CMS may require Part D Sponsors to make appropriate adjustment to its bid submission for a plan year to account for the absence of benefits that were offered under the Model.

Article 9
Order of Precedence & Relationship to Other Agreements

A. This Addendum does not supersede or modify Sections 1860D-1 through 1860D-43 of the Act, or 42 C.F.R. Part 423, except as specifically waived in Appendix 1 of this Addendum for purposes of carrying out this Model.

B. This Addendum specifies additional rights and obligations of the parties with respect to the Model, and does not relieve the parties from, or modify their rights and obligations with respect to, the operation of a prescription drug plan in general or pursuant to the Underlying Contract.

C. If Part D Sponsor also has an agreement to participate in the Medicare Advantage Value-Based Insurance Design Model (MA-VBID) and has proposed to offer rewards and incentives associated with the Part C or Part D benefit under such other model, the following additional requirements apply to the Part D Sponsor under this Model.

1. The Part D Sponsor shall not conduct a Part D RI Program in a Model PBP that conditions eligibility for a reward or incentive on the Targeted Enrollee completing the same healthcare activity (or service) that the enrollee must complete for a reward or incentive to be available to that enrollee under the MA-VBID Model. Upon request, Part D Sponsor shall provide documentation and data related to compliance with this requirement.

2. The Part D Sponsor shall limit the provision of rewards and incentives to each enrollee to a maximum annual aggregate amount of $600.00 for all rewards and incentives under this Model and the MA-VBID Model, and shall include the per unit value of each reward and incentive it offers to a Targeted Enrollee under MA-VBID Model when determining whether a reward or incentive to such Targeted Enrollee would exceed the annual aggregate cap on the total value of rewards and incentives that the Part D Sponsor can provide to a Targeted Enrollee under this Model. Upon request, Part D Sponsor shall provide documentation and data related to compliance with these requirements.

D. In the event of any conflict among the documents or other requirements that govern the conduct of CMS and Part D Sponsor in their administration of or participation in the Model, the order of priority to interpret the obligations of the parties shall be as follows:

1. This Addendum;

2. The Underlying Contract to which this Addendum is attached, and other addenda;

3. Any Model Guidance, including, without limitation, guidance on marketing, data collection and determination of eligibility for risk corridor payments and liability for risk corridor recoveries; and

4. Part D Sponsor's Approved Proposal.

E. The termination of this Addendum by either party shall not, by itself, relieve the parties from their obligations under the Underlying Contract and its other addenda, if any.

Article 10
Attestation of Compliance

Part D Sponsor hereby attests that:

A. The Part D Sponsor will implement their Approved Proposal;

B. Each Model PBP's bid pricing tool (BPT) has been completed in a manner consistent with all CMS guidelines and Model Guidance; and

C. Part D Sponsor has not made changes to the Model PBP's benefit structure, formulary, network, or otherwise that discriminate against enrollees in any Model PBP.

Article 11
Limitation on Review

A. Limitations on Review. There is no administrative or judicial review under sections 1869 or 1878 of the Act or otherwise for the following:

1. The selection of Part D sponsors to participate in the Model, including the decision by CMS to terminate this Addendum or to direct the termination of any Model PBPs;
2. The selection of manufacturers to participate in the Model, including the decision by CMS to terminate a manufacturer's participation in the Model;
3. The elements, parameters, scope, and duration of the Model;
4. Determinations regarding budget neutrality under section 1115A(b)(3);
5. The termination or modification of the design and implementation of a Model under section 1115A(b)(3)(B);
6. Decisions about expansion of the duration and scope of a model under subsection 1115A(c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection; or
7. The determination of a Model PBP's eligibility for the optional first risk corridor.

Article 12
Severability

In the event that one or more of the provisions contained herein shall, for any reason, be held to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability shall not affect any other provisions of this Addendum, but this Addendum shall be construed as if such invalid, illegal or unenforceable provisions had never been contained herein, unless the deletion of such provision or provisions would result in such a

material change so as to cause completion of the transactions contemplated herein to be unreasonable.

Article 13
Miscellaneous

A. Definitions.

Terms not otherwise defined in this Addendum shall have the meaning given such terms in the Underlying Contract, or 42 C.F.R. Part 423, as applicable.

B. Notifications.

All notifications to CMS required under this Addendum shall be submitted by the Part D Sponsor to CMS by electronic mail to PartDSavingsModel@cms.hhs.gov. All notifications to the Part D Sponsor required under this Addendum shall be submitted by CMS to Part D Sponsor by electronic mail either to the person(s) designated in the Approved Proposal or the Health Plan Management System as the Part D Sponsor's primary point of contact, or via a Health Plan Management System broadcast email.

C. Compliance with Laws.

1. The Part D Sponsor shall comply with the applicable terms of this Addendum, the Underlying Contract and all applicable statutes, regulations, and guidance, including without limitation (a) federal criminal laws; (b) the federal False Claims Act (31 U.S.C. § 3729 et seq.); (c) the federal anti-kickback statute (42 U.S.C. § 1320a-7b(b)); (d) the federal civil monetary penalties law (42 U.S.C. § 1320a-7a); (e) the federal physician self-referral law (42 U.S.C. § 1395nn), and (f) applicable State laws.

2. This Addendum does not provide any waivers of the fraud and abuse laws. The Part D Sponsor must comply with all applicable fraud and abuse laws, except as such laws may be waived pursuant to section 1115A(d)(1) of the Act specifically for the Model.

D. Execution in Counterpart.

This Addendum and any amendments hereto may be executed in counterparts, each of which shall be deemed to be an original, but all of which, taken together, shall constitute one and the same agreement. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

E. STAR RATINGS

CMS may adjust the rules for calculating the Star Ratings for MA Organizations and Part D Sponsors participating in the Model to protect against a statistically significant negative impact to the Part C or Part D Star Ratings for MA Organizations and Part D Sponsors that have MA-PDs and stand-alone PDPs not participating in the Model when the impact is directly attributable to participation in the Model.

[SIGNATURE PAGE FOLLOWS]

In witness whereof, the parties hereby execute this Addendum.

This document has been electronically signed by:

FOR THE PART D SPONSOR
<<CONTRACTING_OFFICIAL_NAME >>
Contracting Official Name
<<DATE_STAMP>>
Date
<<CONTRACT_NAME>> <<ADDRESS>>
Organization Address

<<AMY_LARRICK CHAVEZ-VALDEZ_ESIG>>
Amy Larrick Chavez-Valdez
Director
Medicare Drug Benefit
and C & D Data Group,
Center for Medicare

<<DATE_STAMP>>
Date

<<AMY BASSANO_ESIG>>
Amy Bassano
Deputy Director
Center for Medicare and
Medicaid Innovation

<<DATE_STAMP>>
Date

Attachments: Appendix 1 (Waivers of Part D Program Requirements)

Appendix 2 (Part D Rewards and Incentives Programs)

Appendix 1: Waivers of Part D Program Requirements

A. Pursuant to Section 1115A(d)(1) of the Act, in its sole discretion, CMS waives the Medicare Part D statutory and regulatory requirements enumerated in this Appendix 1 for purposes of the Model. These waivers are granted only to the extent necessary to implement the Model. CMS may modify or rescind any or all of these waivers at any time, in its sole discretion.

B. Waivers for Part D Sponsors that are Model Participants. The waivers identified in this Section B are for Part D sponsors participating in the Model. Each waiver in this Section B is: (1) each contingent on compliance with the terms and conditions of this Addendum, the Approved Proposal, and documents incorporated therein; (2) is granted to the Part D Plan Sponsor only as to the Model PBPs and only to the extent necessary to implement the Model in accordance with the Addendum and documents incorporated therein; and (3) is granted only for the term of this Addendum.

1. Special Rule for Supplemental Benefits. The following requirement of section 1860D-14A(c)(2) of the Act and 42 C.F.R. § 423.2325(e): "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.

2. Reduction of First Threshold Risk Percentage. Section 1860D-15(e)(3)(C)(i)(III) of the Act 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 PDP, MA-PD, C-SNP, or I-SNPs).

3. Low Income Cost Sharing Subsidy Calculation. 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.

4. Uniformity and Accessibility of Benefits and Cost Sharing: Section 1860D–2(a) of the Act; and 42 CFR §§ 423.104(b)(2), 423.265(c) to the extent necessary to permit Part D sponsors to offer Model-specific supplemental benefits and Part D RI to non-LIS

enrollees only, subject to the terms of the Model. Model-specific supplemental benefits consist of cost-sharing on Model drugs as described at Article 3, Section C(2)(a) of this addendum, and Part D RI includes any program offer under this Model in compliance with Appendix 2.

5. Tiering Exceptions. 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 Service (AHFS) Drug Information or the DRUGDEX Information System compendia.

6. Prohibition on Mid-year Benefit Enhancements. Requirements under § 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.

C. Waiver for Part D Sponsors. The waivers identified in this Section C are for Part D sponsors, inclusive of Part D sponsors not participating in the Model and is granted only for the duration of the Model.

1. Star Ratings for Part D plans. 42 C.F.R.§§ 423.182-423.186 and 42 C.F.R. 422.162-422.166 to the extent necessary to permit CMS to adjust the rules for calculating the Star Ratings for Part D Sponsors participating in the PDSS Model to protect against a statistically significant negative impact to the Part C and D Star Ratings for MA-PDs and stand-alone PDPs that are not participating in the Model when the impact is directly attributable to participation in the Model;

2. Part D Bid and Payment Data. Section 1860D-15(f) of the Act is waived to the extent necessary to permit CMS to use Part D bid and payment data for purposes of conducting and evaluating the Model.

Appendix 2:
Part D Rewards and Incentives Programs

The Part D Sponsor may, subject to certain conditions and CMS approval, implement a Part D RI Program. The Part D Sponsor shall implement any Part D RI Program under the Part D Senior Savings Model during the term of the Addendum only in accordance with the terms of this Addendum, including this Appendix 2, and the Approved Proposal.

1. Part D Rewards and Incentives Programs Structure and Content

A. If the Part D Sponsor is implementing a Part D RI Program under the Model, the parties acknowledge that Part D Sponsor has submitted as part of its application for participation in the Part D Senior Savings Model, a proposal to offer one or more Part D RI Programs to Targeted Enrollees.

B. Part D Sponsor shall identify Targeted Enrollees for the Part D RI Program without discrimination and using objective criteria that comply with the terms of the Addendum, including this Appendix 2, and are specified in the Approved Proposal or are otherwise approved in writing, in advance by CMS. Such objective criteria must identify the subset of enrollees who would receive the greatest health care value from receiving the benefits or participating in the activities associated with the particular reward or incentive in the Part D RI Program and must include that the enrollee have Diabetes or Pre-diabetes.

C. The Part D Sponsor acknowledges that for each Part D RI Program the Approved Proposal contains the following:

i. The goals of the Part D RI Program;

ii. The list of Model PBPs in which the Part D RI Program will be implemented;

iii. The nature and scope of the Part D RI Program, including the criteria for identifying Targeted Enrollees and the beneficiary engagement methodology;

iv. The eligibility criteria that must be met for an individual Targeted Enrollee to qualify to receive the reward or incentive, including the healthcare activity that must be completed for the reward or incentive to be available, and, if eligibility includes an adherence metric, the specific criteria for measuring adherence and the evidence base to support the clinical appropriateness of the adherence criteria;

v. The type and per unit value of each reward or incentive and the method for providing the reward or incentive to eligible Targeted Enrollees;

vi. The maximum number and frequency of the rewards and incentives that may be obtained by an eligible Targeted Enrollee per year; and

vii. The evidence base and theory of change used to develop the reward or incentive and the expected outcomes of the Part D RI Program(s).

D. The Part D Sponsor shall:

i. Provide the rewards and incentives only to eligible Targeted Enrollees and only in accordance with the Approved Proposal and this Addendum;

ii. Comply with the standards for Rewards and Incentives as outlined in the Medicare Managed Care Manual Ch. 4 § 100 issued and effective April 22, 2016 at available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf except as waived or otherwise modified by the Addendum, including Appendix 1 or this Appendix 2;

iii. Not provide any reward or incentive if its value exceeds the value of the expected impact on enrollee behavior or the expected benefit of the healthcare service or activity on which receipt of the reward or incentive is based, except that (notwithstanding the Rewards and Incentives provisions in the Medicare Managed Care Manual Ch. 4 § 100), the value of the individual reward or incentive may exceed the cost of the health-related service or activity itself, so long as the cost of the health-related service or activity is less than the expected benefit of the health care item or service on which receipt of the reward is based;

iv. Ensure that Part D RI Programs are complete by the end of a plan year. Part D RI programs may allow the enrollee to carry over unspent value of rewards and incentives from one contract year to the next for the enrollee's use, but the Part D Sponsor must not require additional actions by the enrollee in the next plan year to receive that reward or incentive;

v. Ensure that Rewards and incentives are tangible items that align with the purpose of the Part D RI program and must directly benefit the enrollee; and,

vi. Limit the provision of rewards and incentives to each enrollee to a maximum annual aggregate amount of $600.00 for all rewards and incentives in this Model and the MA-VBID Model, and include the per unit value of each reward and incentive it offers to a Targeted Enrollee under the MA-VBID Model when determining whether a reward or incentive to such Targeted Enrollee would exceed the annual aggregate amount on the total value of rewards and incentives that the Part D Sponsor can provide to a Targeted Enrollee under this Model.

E. Part D Sponsor shall ensure that any rewards and incentives in its Part D RI Programs are furnished in accordance with the goals of the program set forth in the Approved Proposal, which must reward or incentivize one or more of the following:

i. Participation of Targeted Enrollees in a disease state management programs specifically for individuals with Pre-diabetes or Diabetes.

ii. Participation in a Part D Sponsor's medication therapy management (MTM) program that includes a focus on a Pre-diabetes or Diabetes.

iii. Receipt by the Targeted Enrollee of preventative health services, such as receiving Part D covered vaccines.

iv. Participation in educational activities designed to enable Targeted Enrollees to better understand their Part D plan benefit, costs, and clinically appropriate coverage alternatives, including biosimilars and generics.

F. In offering any reward or incentive for participation in an MTM program, the Part D Sponsor shall comply with existing CMS requirements for MTM programs, as set forth in 42 C.F.R. § 423.153.

G. In offering any reward or incentive for participation in preventive health services, the Part D Sponsor may design a program with the overall goal of improving medication adherence, however the Part D Sponsor shall not condition any such reward or incentive solely on prescription fills or clinical outcomes, and shall not furnish any such reward or incentive for a service that is not clinically indicated for the beneficiary.

H. In implementing and operating its Part D RI Program, the Part D Sponsor shall not:

i. Provide a reward or incentive to a Medicare beneficiary who is not enrolled in a Model PBP.

ii. Provide a reward or incentive to an enrollee in a Model PBP who does not have a Diabetes or Pre-diabetes.

iii. Provide a reward or incentive to an enrollee in a Model PBP in connection with the same healthcare activity or service that the enrollee completed to be eligible for a reward or incentive under the MA-VBID Model.

iv. Structure a Part D RI Program to discourage clinically indicated medication use.

v. Use a Part D RI Program largely to market a PBP or encourage beneficiaries to remain with a specific plan.

vi. Use a Part D RI Program to, in any way, choose or solicit healthier enrollees over enrollees who the sponsors believe may be less healthy.

vii. Create a Part D RI Program that discriminates 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.

viii. Provide rewards or incentives in the form of cash, cash equivalents, or other monetary rebates, or use rewards or incentives to decrease cost-sharing or plan premium;

ix. Identify Targeted Enrollees based on the identity of their pharmacy provider.

x. Use a Part D RI Program that is designed to allow for rewards and incentives to be won based on probability;

xi. Use prescription fills or adherence as the sole basis for providing a reward or incentive.

xii. Incentivize enrollees to use mail service pharmacies, preferred pharmacies, or any other specific network providers.

xiii. Receive or use funding, in-kind resources, or any kind of remuneration provided directly or indirectly by a drug manufacturer. This includes, but is not limited to, the use of personnel affiliated with a drug manufacturer, or manufacturer-financed coupons or discounts provided to a beneficiary.

xiv. Receive or use funding, in-kind resources, or any kind of remuneration provided directly or indirectly by a pharmacy or entity that owns or operates pharmacies. This includes use of personnel affiliated with a pharmacy, or pharmacy-financed coupons or other discounts provided to a beneficiary.

2. Record Retention and Reporting

A. In accordance with Article 5 of this Addendum, the Part D Sponsor shall maintain the following records regarding each Part D RI Program (and may be required to report such records):

i. The identity of each Targeted Enrollee, including enrollees identified with Diabetes or Pre-Diabetes, and the total number of Targeted Enrollees;

ii. The identity of each enrollee who received a reward and incentive, including enrollees identified with Diabetes or Pre-diabetes, and the total number of enrollees who received a reward and/or incentive;

iii. The Part D RI Program pursuant to which the enrollee received the reward or incentive;

iv. The nature and date(s) of the activities or other conduct engaged in by the enrollee and clinical information about the enrollee that enabled the enrollee to qualify for the reward or incentive;

v. The nature and amount of the reward or incentive received by the enrollee;

vi. The cost of the healthcare activities or services with which eligibility for a reward or incentive is associated, the value of the expected impact on enrollee behavior, and the value of the benefit of the healthcare activity on which receipt of the reward or incentive is based;

vii. Any trends over time in the number of Targeted Enrollees in the RI program, or the number of enrollees who received a reward and/or incentive; and,

viii. Any evaluations done by the Part D Sponsor to assess the effectiveness of the RI Program.

B. The Part D Sponsor shall submit reports to CMS, in a form and manner and by a deadline specified by CMS, regarding its implementation of each Part D RI Program. The Part D Sponsor shall provide CMS with supplemental information upon request regarding its implementation of any Part D RI Program.

3. Compliance and Enforcement

A. Part D Sponsor shall have in place a protocol for monitoring the implementation and administration of each Part D RI Program. Part D Sponsor shall make this protocol available to CMS upon request.

B. CMS may terminate or suspend the Part D Sponsor's implementation of any Part D RI Program, or take other remedial action in accordance with Article 6 of the Addendum, including without limitation if –

i. The Part D Sponsor fails to comply with the terms and conditions of the Addendum or this Appendix 2; or

ii. CMS determines that the Part D Sponsor's implementation of such a program might compromise the integrity of the Model.

C. Without limiting the foregoing, the parties agree that if CMS determines that the Part D Sponsor has failed to comply with the terms of Article 3 of this Addendum or this Appendix 2, CMS may prohibit the Part D Sponsor from offering Part D RI Programs in one or more future plan years, regardless of whether the Part D Sponsor has corrected or otherwise resolved the noncompliance.