

ADDENDUM TO THE MEDICARE COVERAGE GAP DISCOUNT PROGRAM AGREEMENT
FOR PARTICIPATION IN THE PART D SENIOR SAVINGS MODEL
(the “Model”)

The Secretary of Health and Human Services (the “Secretary”) and the Manufacturer participating in the Medicare Coverage Gap Discount Program as identified in Article XI of this Addendum (the “Manufacturer”), agree to amend the contract identified in Article XI of this Addendum, including all exhibits, attachments addenda and amendments thereto, (“Underlying Contract”), governing the Manufacturer’s participation in the Coverage Gap Discount Program pursuant to §§ 1860D-14A and 1860D-43 of the Social Security Act (“the Act”) to include this Addendum to provide for the Manufacturer’s participation in the Part D Senior Savings 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 commencing with plan year 2021. The purpose of this Model is to test a change to the Manufacturer Coverage Gap Discount Program to allow Part D sponsors, through eligible enhanced alternative plans, to offer a Part D benefit design that includes predictable, standard copays in the deductible, initial coverage, and coverage gap phases by offering supplemental benefits that apply after manufacturers provide a discounted price for applicable drugs included in the Model.

Therefore, the Secretary and Manufacturer (“the parties”) hereby agree as follows:

Article I

Definitions

A. Terms not otherwise defined in this Addendum shall have the meaning given to such terms in the Underlying Contract.

B. The following terms in the Underlying Contract are amended to read as follows:

1. “Applicable Discount” means:

- (i) For a plan year 2011 to 2018, fifty percent of the negotiated price (as defined in section I(m), of this agreement), of the applicable drug of a Manufacturer that falls within the coverage gap (as defined in section I(e) of this agreement) and that remains after the negotiated price is reduced by any Part D supplemental benefits that are available;
- (ii) with respect to a plan year 2018 to 2020 and a plan year after 2025, seventy percent of the negotiated price (as defined in section I(m) of this agreement), of the applicable drug of a Manufacturer that falls within the coverage gap (as defined in section I(e) of this agreement) and that remains after the negotiated price is reduced by any Part D supplemental benefits that are available;
- (iii) with respect to a plan year 2021 to 2025, seventy percent of the negotiated price (as defined in section I(m) of this agreement), of the applicable drug of a

Manufacturer that falls within the coverage gap (as defined in section I(e) of this agreement) and that remains after the negotiated price is reduced by any Part D supplemental benefits that are available, provided however that such reduction by Part D Supplemental benefits shall not apply to the negotiated price of a Model Drug for a Model Beneficiary.

2. "Discount Program" means the Medicare Coverage Gap Discount Program established under section 1860D-14A of the Act inclusive of the Model.
- C. The terms defined in this section, for purposes of this Model, have the meanings specified as follows:
1. "Enhanced Alternative Coverage" has the meaning set forth in 42 CFR § 423.100.
 2. "Model PBP" stands for Model plan benefit package and means each Part D plan that provides enhanced alternative coverage that CMS has approved to participate in the Model.
 3. "Model Beneficiary" means an Applicable Beneficiary as defined in 42 CFR § 423.100 enrolled in a Model PBP.
 4. "Model Drug" means any Applicable Drug of the Manufacturer that is, or contains, a drug classified as insulin in American Hospital Formulary Service (AHFS) Drug Information or the DRUGDEX Information System compendia.
 5. "Special Rule for Supplemental Benefits" means § 1860D-14A(c)(2) of the Act.

Article II

Manufacturer's Responsibilities

A. OBLIGATIONS FOR MODEL DRUGS

1. The Manufacturer agrees that Appendix I of this Addendum lists all currently marketed NDCs of the Manufacturer's Model Drugs and agrees to promptly update such list with any additional NDCs.
2. The Manufacturer shall comply with all obligations in the Underlying Contract with respect to Model Drugs, including without limitation the obligation to reimburse all Applicable Discounts provided by Part D Sponsors for all Model Drugs without regard to the Special Rule for Supplemental Benefits.

B. DATA REPORTING & COOPERATION WITH MONITORING AND EVALUATION

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

evaluation. The obligation to cooperate in Model-related monitoring, auditing, and evaluation shall survive termination of the Manufacturer's participation in the Model.

2. The Manufacturer 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. The Manufacturer shall comply with any instructions regarding the collection and submission of data regarding the Manufacturer's participation in Model. CMS will make a reasonable effort to limit data submission from the Manufacturer to data that are not readily available to CMS. CMS will not require information from the Manufacturer regarding any rebates or price concessions negotiated with Part D Sponsors as part of Model-related monitoring, auditing, and evaluation.
3. For the purposes of monitoring, the Manufacturer shall provide CMS, within 30 (thirty) calendar days of execution of this Addendum, the wholesale acquisition cost (WAC) of each NDC of each Model Drug and, for the term of the Addendum, provide CMS written notice within 30 (thirty) calendar days of any change in the WAC of the NDC of a Model Drug. Such notice shall include the date of the change, the previous WAC, and the new WAC. The Manufacturer acknowledges that WAC data is required by CMS to implement and evaluate the Model.

C. OTHER MODEL IMPLEMENTATION REQUIREMENTS

Manufacturer shall:

1. Comply with all applicable laws governing its operation and participation in the Discount Program, except as specifically waived in writing for this Model in accordance with section 1115A(d) of the Act.
2. Not provide or offer funding, in kind resources, or any remuneration directly or indirectly to a Part D Sponsor related to the implementation or operation of any Part D rewards and incentives program.
3. Not take any action that results in Part D Sponsor non-compliance with applicable laws, the requirements of the Part D Program, or this Model.

Article III

Secretary's Responsibilities

- A. The Secretary shall comply with the obligations in the Underlying Contract with respect to Model Drugs, except as necessary for the efficient administration of Part D Program.
- B. The Secretary shall make public on the Model website the manufacturer name and the class(es) of Model Drugs participating in the Model.

Article IV

Term and Renewal

A. TERM OF UNDERLYING CONTRACT

The parties hereby renew the Underlying Contract for the one-year period that begins on January 1, 2021.

B. TERM OF ADDENDUM

The term of this Addendum begins on the date it was executed by the Secretary's authorized representative and ends on December 31, 2021, unless this Addendum is sooner terminated under Article V of this Agreement.

C. RENEWAL

This Addendum automatically renews upon renewal of the Underlying Contract for a period of one (1) year starting on January 1, 2022. This Addendum automatically renews thereafter upon renewal of the Underlying Contract, except that this Addendum shall not remain in effect after December 31, 2025.

Article V

Modification and Termination of Addendum

A. ADDENDUM MODIFICATION

1. This Addendum may be modified at any time by written mutual consent of the parties.
2. The Secretary may modify this Addendum without the consent of the Manufacturer for good cause or as necessary to comply with applicable federal or state law, or regulatory requirements. To the extent practicable, the Secretary shall provide the Manufacturer with 30 calendar days advance written notice of any such unilateral amendment, which notice shall specify the amendment's effective date.

B. ADDENDUM TERMINATION BY MANUFACTURER

The Manufacturer may terminate its participation in the Model for any reason. Any termination shall be effective as of the day after the end of the calendar year if notice of termination is sent before January 30 of a calendar year or as of the day after the end of the succeeding calendar year if the notice of termination is sent on or after January 30 of the calendar year.

C. TERMINATION BY MUTUAL CONSENT

This Addendum may be terminated at any time by written mutual consent of the parties.

D. TERMINATION OF ADDENDUM BY THE SECRETARY

1. The Secretary may terminate this Addendum with or without advance notice if:
 - a. CMS terminates the Model pursuant to Section 1115A(b)(3)(B) of the Act or otherwise
 - b. CMS determines that the Manufacturer:
 - 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 implement or fully comply with the terms of a corrective action plan or other intermediate sanction;
 - iv. Has submitted false data or made false representations, warranties, attestations or certifications in connection with any aspect of the Model;
 - v. Is subject to sanctions or other enforcement or correction actions of a federal, state, or local government agency;
 - vi. Assigned or purported to assign any of the rights or obligations under this Addendum, voluntarily or involuntarily, whether by merger, consolidation, dissolution, operation of law, or any other manner, without the written consent of the Secretary; or
 - vii. 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 the Secretary
2. Prior to terminating the Addendum this Article V.D, CMS may afford the Manufacturer an opportunity develop and implement a corrective action plan to correct deficiencies. In addition to any sanction or penalty authorized under 42 C.F.R. 423.2340, the Secretary may restrict the Manufacturer's participation in the Model (e.g., restrict which of Manufacturer's drugs are Model Drugs) if the Secretary determines that an event identified in Paragraph D1b of this Article has occurred.

E. AUTOMATIC TERMINATION

This Addendum terminates automatically as of the effective date of termination of the Underlying Contract.

Article VI

Effects of Termination and Expiration and Surviving Obligations

- A. The Manufacturer shall ensure timely transfer of any data or files to the Secretary necessary for monitoring, assessment, transition or close out of the Manufacturer's Model-related activities and shall comply with all other CMS-specified close out procedures.
- B. 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.
- C. Upon termination of this Addendum, the Manufacturer shall continue to reimburse all applicable discounts and comply with all other obligations under the Underlying Contract consistent with applicable law and the Underlying Contract as if this Addendum had never been executed.

Article VII

Order of Precedence and Relationship to Other Agreements

- A. This Addendum does not supersede or modify Sections 1860D-1 through 1860D-43 of the Act or 42 CFR Part 423, except as specifically waived in Appendix 2 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 only, and does not relieve the parties from, or modify their rights and obligations with respect to, the operation of Discount Program in general or pursuant to the Underlying Contract except as expressly stated herein.
- C. In the event of any conflict among the documents or other requirements that govern the conduct of the Secretary, CMS and Manufacturer 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; and
 - 3. Any Model-related guidance issued by the Secretary or CMS.
- D. 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 VIII

Limitation 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 manufacturers to participate in the Model, including the decision by the Secretary to terminate this Addendum;
2. The selection of Part D Sponsors to participate in the Model, including the approval of Model PBPs;
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); or
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.

Article IX

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 X

General Provisions

A. NOTIFICATIONS

1. Any notice to the Secretary relative to the Model must be sent to the Model email address at PartDSavingsModel@cms.hhs.gov.
2. Any notice to the Manufacturer relative to the Model will be sent to the main point of contact identified in Article XI.

B. RECORDS MAINTENANCE AND ACCESS

The Manufacturer shall maintain records relating to the Model for 10 years. The Manufacturer shall provide access to such records in accordance with the provisions of the Underlying Contract.

C. COMPLIANCE WITH LAWS

1. The Manufacturer shall comply with all 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.

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.

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Appendix 1: Model Drugs

Manufacturer Name	DUNS # (XXXXXXXXXX)	Unique ID (PXXXX)
Active FDA-assigned labeler codes(s) (Yes/No?)		
Labeler Code	Firm Name	
Model Drug NDC Package Code (XXXXX-XXXX-XX)	Model Drug Name (Proprietary Name, Non-Proprietary Name, Strength, Dosage Form)	

Appendix 2: 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 2 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 Manufacturers that are Model Participants. The waivers identified in this paragraph B are for Manufacturers participating in the Model. Each waiver in this paragraph B is (1) each contingent on compliance with the terms and conditions of this Addendum and documents incorporated therein; (2) is granted to the Manufacturer 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:** Section 1860D-14A(c)(2) 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.
 2. **Underlying Contract Renewal:** 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.
 3. **Modification to Underlying Contract:** 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.