H. R. ____

To amend title XVIII of the Social Security Act to provide for a cap on beneficiary liability under part D of the Medicare program, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

Mr. HORSFORD introduced the following bill; which was referred to the Committee on ____________________________

A BILL

To amend title XVIII of the Social Security Act to provide for a cap on beneficiary liability under part D of the Medicare program, and for other purposes.

Be it enacted by the Senate and House of Representa-
tives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the “Capping Drug Costs for Seniors Act of 2021”. 
SEC. 2. MEDICARE PART D BENEFIT REDESIGN.

(a) BENEFIT STRUCTURE REDESIGN.—Section 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–102(b)) is amended—

(1) in paragraph (2)—

(A) in subparagraph (A), in the matter preceding clause (i), by inserting “for a year preceding 2022 and for costs above the annual deductible specified in paragraph (1) and up to the annual out-of-pocket threshold specified in paragraph (4)(B) for 2022 and each subsequent year” after “paragraph (3)”; 

(B) in subparagraph (C)—

(i) in clause (i), in the matter preceding subclause (I), by inserting “for a year preceding 2022,” after “paragraph (4),”; and 

(ii) in clause (ii)(III), by striking “and each subsequent year” and inserting “and 2021”; and

(C) in subparagraph (D)—

(i) in clause (i)—

(I) in the matter preceding subclause (I), by inserting “for a year preceding 2022,” after “paragraph (4),”; and
(II) in subclause (I)(bb), by striking “a year after 2018” and inserting “each of years 2018 through 2021”; and

(ii) in clause (ii)(V), by striking “2019 and each subsequent year” and inserting “each of years 2019 through 2021”;

(2) in paragraph (3)(A)—

(A) in the matter preceding clause (i), by inserting “for a year preceding 2022,” after “and (4),”; and

(B) in clause (ii), by striking “for a subsequent year” and inserting “for each of years 2007 through 2021”; and

(3) in paragraph (4)—

(A) in subparagraph (A)—

(i) in clause (i)—

(I) by redesignating subclauses (I) and (II) as items (aa) and (bb), respectively, and moving the margin of each such redesignated item 2 ems to the right;

(II) in the matter preceding item (aa), as redesignated by subclause (I),
by striking “is equal to the greater of—” and inserting “is equal to—

“(I) for a year preceding 2022, the greater of—”; (III) by striking the period at the end of item (bb), as redesignated by subclause (I), and inserting “; and”; and

(IV) by adding at the end the following:

“(II) for 2022 and each succeeding year, $0.”; and

(ii) in clause (ii)—

(I) by striking “clause (i)(I)” and inserting “clause (i)(I)(aa)”; and

(II) by adding at the end the following new sentence: “The Secretary shall continue to calculate the dollar amounts specified in clause (i)(I)(aa), including with the adjustment under this clause, after 2021 for purposes of section 1860D–14(a)(1)(D)(iii).”;

(B) in subparagraph (B)—

(i) in clause (i)—
(I) in subclause (V), by striking “or” at the end;

(II) in subclause (VI)—

(aa) by striking “for a sub-
sequent year” and inserting “for
2021”; and

(bb) by striking the period
at the end and inserting a semi-
colon; and

(III) by adding at the end the
following new subclauses:

“(VII) for 2022, is equal to
$2,000; or

“(VIII) for a subsequent year, is
equal to the amount specified in this
subparagraph for the previous year,
increased by the annual percentage in-
crease described in paragraph (6) for
the year involved.”; and

(ii) in clause (ii), by striking “clause
(i)(II)” and inserting “clause (i)”;

(C) in subparagraph (C)(i), by striking
“and for amounts” and inserting “and, for a
year preceding 2022, for amounts”; and
(D) in subparagraph (E), by striking “In applying” and inserting “For each of years 2011 through 2021, in applying”.

(b) DECREASING REINSURANCE PAYMENT AMOUNT.—Section 1860D–15(b)(1) of the Social Security Act (42 U.S.C. 1395w–115(b)(1)) is amended by inserting after “80 percent” the following: “(or, with respect to a coverage year after 2021, 20 percent)”.

(e) MANUFACTURER DISCOUNT PROGRAM.—

(1) IN GENERAL.—Part D of title XVIII of the Social Security Act (42 U.S.C. 1395w–101 et seq.) is amended by inserting after section 1860D–14A the following new section:

“SEC. 1860D–14B. MANUFACTURER DISCOUNT PROGRAM.

“(a) ESTABLISHMENT.—The Secretary shall establish a manufacturer discount program (in this section referred to as the ‘program’). Under the program, the Secretary shall enter into agreements described in subsection (b) with manufacturers and provide for the performance of the duties described in subsection (e). The Secretary shall establish a model agreement for use under the program by not later than July 1, 2021, in consultation with manufacturers, and allow for comment on such model agreement.

“(b) TERMS OF AGREEMENT.—
“(1) IN GENERAL.—

“(A) AGREEMENT.—An agreement under this section shall require the manufacturer to provide applicable beneficiaries access to discounted prices for applicable drugs of the manufacturer that are dispensed on or after January 1, 2022.

“(B) PROVISION OF DISCOUNTED PRICES AT THE POINT-OF-SALE.—The discounted prices described in subparagraph (A) shall be provided to the applicable beneficiary at the pharmacy or by the mail order service at the point-of-sale of an applicable drug.

“(C) TIMING OF AGREEMENT.—

“(i) SPECIAL RULE FOR 2022.—In order for an agreement with a manufacturer to be in effect under this section with respect to the period beginning on January 1, 2022, and ending on December 31, 2022, the manufacturer shall enter into such agreement not later than 30 days after the date of the establishment of a model agreement under subsection (a).

“(ii) 2023 AND SUBSEQUENT YEARS.—In order for an agreement with a
manufacturer to be in effect under this section with respect to plan year 2023 or a subsequent plan year, the manufacturer shall enter into such agreement (or such agreement shall be renewed under paragraph (4)(A)) not later than January 30 of the preceding year.

“(2) Provision of appropriate data.—Each manufacturer with an agreement in effect under this section shall collect and have available appropriate data, as determined by the Secretary, to ensure that it can demonstrate to the Secretary compliance with the requirements under the program.

“(3) Compliance with requirements for administration of program.—Each manufacturer with an agreement in effect under this section shall comply with requirements imposed by the Secretary or a third party with a contract under subsection (d)(3), as applicable, for purposes of administering the program, including any determination under subparagraph (A) of subsection (c)(1) or procedures established under such subsection (c)(1).

“(4) Length of agreement.—

“(A) In general.—An agreement under this section shall be effective for an initial pe-
period of not less than 12 months and shall be automatically renewed for a period of not less than 1 year unless terminated under subparagraph (B).

“(B) TERMINATION.—

“(i) BY THE SECRETARY.—The Secretary may provide for termination of an agreement under this section for a knowing and willful violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 30 days after the date of notice to the manufacturer of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, and such hearing shall take place prior to the effective date of the termination with sufficient time for such effective date to be repealed if the Secretary determines appropriate.

“(ii) BY A MANUFACTURER.—A manufacturer may terminate an agreement under this section for any reason. Any such termination shall be effective, with respect to a plan year—
“(I) if the termination occurs before January 30 of a plan year, as of the day after the end of the plan year; and

“(II) if the termination occurs on or after January 30 of a plan year, as of the day after the end of the succeeding plan year.

“(iii) Effectiveness of Termination.—Any termination under this subparagraph shall not affect discounts for applicable drugs of the manufacturer that are due under the agreement before the effective date of its termination.

“(iv) Notice to Third Party.—The Secretary shall provide notice of such termination to a third party with a contract under subsection (d)(3) within not less than 30 days before the effective date of such termination.

“(c) Duties Described.—The duties described in this subsection are the following:

“(1) Administration of Program.—Administering the program, including—
“(A) the determination of the amount of the discounted price of an applicable drug of a manufacturer;

“(B) the establishment of procedures under which discounted prices are provided to applicable beneficiaries at pharmacies or by mail order service at the point-of-sale of an applicable drug;

“(C) the establishment of procedures to ensure that, not later than the applicable number of calendar days after the dispensing of an applicable drug by a pharmacy or mail order service, the pharmacy or mail order service is reimbursed for an amount equal to the difference between—

“(i) the negotiated price of the applicable drug; and

“(ii) the discounted price of the applicable drug;

“(D) the establishment of procedures to ensure that the discounted price for an applicable drug under this section is applied before any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the pur-
chase or provision of prescription drug coverage
on behalf of applicable beneficiaries as the Sec-
retary may specify; and

“(E) providing a reasonable dispute resolu-
tion mechanism to resolve disagreements be-
tween manufacturers, applicable beneficiaries,
and the third party with a contract under sub-
section (d)(3).

“(2) MONITORING COMPLIANCE.—

“(A) IN GENERAL.—The Secretary shall
monitor compliance by a manufacturer with the
terms of an agreement under this section.

“(B) NOTIFICATION.—If a third party
with a contract under subsection (d)(3) deter-
mines that the manufacturer is not in compli-
ance with such agreement, the third party shall
notify the Secretary of such noncompliance for
appropriate enforcement under subsection (e).

“(3) COLLECTION OF DATA FROM PRESCRIP-
tion DRUG PLANS AND MA–PD PLANS.—The Sec-
retary may collect appropriate data from prescrip-
tion drug plans and MA–PD plans in a timeframe
that allows for discounted prices to be provided for
applicable drugs under this section.

“(d) ADMINISTRATION.—
“(1) IN GENERAL.—Subject to paragraph (2),
the Secretary shall provide for the implementation of
this section, including the performance of the duties
described in subsection (c).

“(2) LIMITATION.—In providing for the imple-
mentation of this section, the Secretary shall not re-
ceive or distribute any funds of a manufacturer
under the program.

“(3) CONTRACT WITH THIRD PARTIES.—The
Secretary shall enter into a contract with one or
more third parties to administer the requirements
established by the Secretary in order to carry out
this section. At a minimum, the contract with a
third party under the preceding sentence shall re-
quire that the third party—

“(A) receive and transmit information be-
tween the Secretary, manufacturers, and other
individuals or entities the Secretary determines
appropriate;

“(B) receive, distribute, or facilitate the
distribution of funds of manufacturers to ap-
propriate individuals or entities in order to
meet the obligations of manufacturers under
agreements under this section;
“(C) provide adequate and timely information to manufacturers, consistent with the agreement with the manufacturer under this section, as necessary for the manufacturer to fulfill its obligations under this section; and

“(D) permit manufacturers to conduct periodic audits, directly or through contracts, of the data and information used by the third party to determine discounts for applicable drugs of the manufacturer under the program.

“(4) PERFORMANCE REQUIREMENTS.—The Secretary shall establish performance requirements for a third party with a contract under paragraph (3) and safeguards to protect the independence and integrity of the activities carried out by the third party under the program under this section.

“(5) IMPLEMENTATION.—The Secretary may implement the program under this section by program instruction or otherwise.

“(6) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the program under this section.

“(e) ENFORCEMENT.—
“(1) AUDITS.—Each manufacturer with an agreement in effect under this section shall be subject to periodic audit by the Secretary.

“(2) CIVIL MONEY PENALTY.—

“(A) IN GENERAL.—The Secretary may impose a civil money penalty on a manufacturer that fails to provide applicable beneficiaries discounts for applicable drugs of the manufacturer in accordance with such agreement for each such failure in an amount the Secretary determines is commensurate with the sum of—

“(i) the amount that the manufacturer would have paid with respect to such discounts under the agreement, which will then be used to pay the discounts which the manufacturer had failed to provide; and

“(ii) 25 percent of such amount.

“(B) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).
“(f) **Clarification Regarding Availability of Other Covered Part D Drugs.**—Nothing in this section shall prevent an applicable beneficiary from purchasing a covered part D drug that is not an applicable drug (including a generic drug or a drug that is not on the formulary of the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in).

“(g) **Definitions.**—In this section:

“(1) **Applicable Beneficiary.**—The term ‘applicable beneficiary’ means an individual who, on the date of dispensing a covered part D drug—

“(A) is enrolled in a prescription drug plan or an MA–PD plan;

“(B) is not enrolled in a qualified retiree prescription drug plan; and

“(C) has incurred costs for covered part D drugs in the year that are equal to or exceed the annual deductible specified in section 1860D–2(b)(1) for such year.

“(2) **Applicable Drug.**—The term ‘applicable drug’, with respect to an applicable beneficiary means a covered part D drug—

“(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 bio-
logic product, licensed under section 351 of the Public Health Service Act; 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 the PDP sponsor of the prescription drug plan or the MA organization offering the MA–PD plan does not use a formulary, for which benefits are available under the prescription drug plan or MA–PD plan that the applicable beneficiary is enrolled in; or

“(iii) is provided through an exception or appeal.

“(3) APPLICABLE NUMBER OF CALENDAR DAYS.—The term ‘applicable number of calendar days’ means—

“(A) with respect to claims for reimbursement submitted electronically, 14 days; and

“(B) with respect to claims for reimbursement submitted otherwise, 30 days.

“(4) DISCOUNTED PRICE.—
“(A) IN GENERAL.—The term ‘discounted price’ means, with respect to an applicable drug of a manufacturer furnished during a year to an applicable beneficiary—

“(i) who has not incurred costs for covered part D drugs in the year that are equal to or exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year, 90 percent of the negotiated price of such drug; and

“(ii) who has incurred such costs in the year that are equal to or exceed such threshold for the year, 70 percent of the negotiated price of such drug.

“(B) CLARIFICATION.—Nothing in this section shall be construed as affecting the responsibility of an applicable beneficiary for payment of a dispensing fee for an applicable drug.

“(C) SPECIAL CASE FOR CERTAIN CLAIMS.—

“(i) CLAIMS SPANNING DEDUCTIBLE.—In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not
fall at or above the annual deductible specified in section 1860D–2(b)(1) for the year, the manufacturer of the applicable drug shall provide the discounted price under this section on only the portion of the negotiated price of the applicable drug that falls at or above such annual deductible.

“(ii) CLAIMS SPANNING OUT-OF-POCKET THRESHOLD.—In the case where the entire amount of the negotiated price of an individual claim for an applicable drug with respect to an applicable beneficiary does not fall entirely below or entirely above the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B)(i) for the year, the manufacturer of the applicable drug shall provide the discounted price—

“(I) in accordance with subparagraph (A)(i) on the portion of the negotiated price of the applicable drug that falls below such threshold; and

“(II) in accordance with subparagraph (A)(ii) on the portion of such
price of such drug that falls at or above such threshold.

“(5) MANUFACTURER.—The term ‘manufacturer’ means any entity which is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis. Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

“(6) NEGOTIATED PRICE.—The term ‘negotiated price’ has the meaning given such term in section 423.100 of title 42, Code of Federal Regulations (as in effect on the date of enactment of section 1860D–14A), except that such negotiated price shall not include any dispensing fee for the applicable drug.

“(7) QUALIFIED RETIREE PRESCRIPTION DRUG PLAN.—The term ‘qualified retiree prescription drug plan’ has the meaning given such term in section 1860D–22(a)(2).”.

(2) SUNSET OF MEDICARE COVERAGE GAP DISCOUNT PROGRAM.—Section 1860D–14A of the So-
Social Security Act (42 U.S.C. 1395-114a) is amended—

(A) in subsection (a), in the first sentence, by striking “The Secretary” and inserting “Subject to subsection (h), the Secretary”; and

(B) by adding at the end the following new subsection:

“(h) SUNSET OF PROGRAM.—

“(1) IN GENERAL.—The program shall not apply with respect to applicable drugs dispensed on or after January 1, 2022, and, subject to paragraph (2), agreements under this section shall be terminated as of such date.

“(2) CONTINUED APPLICATION FOR APPLICABLE DRUGS DISPENSED PRIOR TO SUNSET.—The provisions of this section (including all responsibilities and duties) shall continue to apply after January 1, 2022, with respect to applicable drugs dispensed prior to such date.”.

(3) INCLUSION OF ACTUARIAL VALUE OF MANUFACTURER DISCOUNTS IN BIDS.—Section 1860D–11 of the Social Security Act (42 U.S.C. 1395w–111) is amended—

(A) in subsection (b)(2)(C)(iii)—
(i) by striking “assumptions regarding the reinsurance” an inserting “assumptions regarding—

“(I) the reinsurance”; and

(ii) by adding at the end the following:

“(II) for 2022 and each subsequent year, the manufacturer discounts provided under section 1860D–14B subtracted from the actuarial value to produce such bid; and”; and

(B) in subsection (c)(1)(C)—

(i) by striking “an actuarial valuation of the reinsurance” and inserting “an actuarial valuation of—

“(i) the reinsurance”;

(ii) in clause (i), as inserted by clause (i) of this subparagraph, by adding “and” at the end; and

(iii) by adding at the end the following:

“(ii) for 2022 and each subsequent year, the manufacturer discounts provided under section 1860D–14B;”.

(d) CONFORMING AMENDMENTS.—
(1) Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102) is amended—

   (A) in subsection (a)(2)(A)(i)(I), by striking “, or an increase in the initial” and inserting “or, for a year preceding 2022, an increase in the initial”;

   (B) in subsection (c)(1)(C)—

      (i) in the subparagraph heading, by striking “AT INITIAL COVERAGE LIMIT”;

      and

      (ii) by inserting “for a year preceding 2022 or the annual out-of-pocket threshold specified in subsection (b)(4)(B) for the year for 2022 and each subsequent year” after “subsection (b)(3) for the year” each place it appears; and

   (C) in subsection (d)(1)(A), by striking “or an initial” and inserting “or, for a year preceding 2022, an initial”.

(2) Section 1860D–4(a)(4)(B)(i) of the Social Security Act (42 U.S.C. 1395w–104(a)(4)(B)) is amended by striking “the initial” and inserting “for a year preceding 2022, the initial”.

(3) Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)) is amended—
(A) in paragraph (1)—

(i) in subparagraph (C), by striking “The continuation” and inserting “For a year preceding 2022, the continuation”; and


(iii) in subparagraph (E), by striking “The elimination” and inserting “For a year preceding 2022, the elimination”; and

(B) in paragraph (2)—

(i) in subparagraph (C), by striking “The continuation” and inserting “For a year preceding 2022, the continuation”; and

(ii) in subparagraph (E)—

(I) by inserting “for a year preceding 2022,” after “subsection (c);” and


(4) Section 1860D–21(d)(7) of the Social Security Act (42 U.S.C. 1395w–131(d)(7)) is amended


(A) by striking “the value of any discount” and inserting the following: “the value of—

“(i) for years prior to 2022, any discount”;

(B) in clause (i), as inserted by subparagraph (A) of this paragraph, by striking the period at the end and inserting “; and”; and

(C) by adding at the end the following new clause:

“(ii) for 2022 and each subsequent year, any discount provided pursuant to section 1860D–14B.”.

(6) Section 1860D–41(a)(6) of the Social Security Act (42 U.S.C. 1395w–151(a)(6)) is amended—

(A) by inserting “for a year before 2022” after “1860D–2(b)(3)”; and

(B) by inserting “for such year” before the period.
Paragraph (1) of section 1860D–43(a) of the Social Security Act (42 U.S.C. 1395w–153(a)) is amended to read as follows:

“(1) participate in—

“(A) for 2011 through 2021, the Medicare coverage gap discount program under section 1860D–14A; and

“(B) for 2022 and each subsequent year, the manufacturer discount program under section 1860D–14B;”.

(e) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan year 2022 and subsequent plan years.