

116TH CONGRESS
1ST SESSION

H. R. 4649

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

OCTOBER 11, 2019

Mr. HORSFORD (for himself and Ms. KENDRA S. HORN of Oklahoma) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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.

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

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Capping Drug Costs
5 for Seniors Act of 2019”.

1 **SEC. 2. MEDICARE PART D BENEFIT REDESIGN.**

2 (a) BENEFIT STRUCTURE REDESIGN.—Section
3 1860D–2(b) of the Social Security Act (42 U.S.C. 1395w–
4 102(b)) is amended—

5 (1) in paragraph (2)—

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

13 (B) in subparagraph (C)—

14 (i) in clause (i), in the matter pre-
15 ceding subclause (I), by inserting “for a
16 year preceding 2022,” after “paragraph
17 (4),”; and

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

21 (C) in subparagraph (D)—

22 (i) in clause (i)—

23 (I) in the matter preceding sub-
24 clause (I), by inserting “for a year
25 preceding 2022,” after “paragraph
26 (4),”; and

9 (2) in paragraph (3)(A)—

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

13 (B) in clause (ii), by striking “for a subse-
14 quent year” and inserting “for each of years
15 2007 through 2021”; and

16 (3) in paragraph (4)—

17 (A) in subparagraph (A)—

18 (i) in clause (i)—

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

24 (II) in the matter preceding item
25 (aa), as redesignated by subclause (I),

1 by striking “is equal to the greater
2 of—” and inserting “is equal to—
3 “(I) for a year preceding 2022,
4 the greater of—”;
5 (III) by striking the period at the
6 end of item (bb), as redesignated by
7 subclause (I), and inserting “; and”;
8 and
9 (IV) by adding at the end the fol-
10 lowing:
11 “(II) for 2022 and each suc-
12 ceeding year, \$0.”; and
13 (ii) in clause (ii)—
14 (I) by striking “clause (i)(I)” and
15 inserting “clause (i)(I)(aa)”; and
16 (II) by adding at the end the fol-
17 lowing new sentence: “The Secretary
18 shall continue to calculate the dollar
19 amounts specified in clause (i)(I)(aa),
20 including with the adjustment under
21 this clause, after 2021 for purposes of
22 section 1860D–14(a)(1)(D)(iii).”;
23 (B) in subparagraph (B)—
24 (i) in clause (i)—

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

3 (II) in subclause (VI)—

4 (aa) by striking “for a sub-
5 sequent year” and inserting “for
6 2021”; and

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

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

22 (C) in subparagraph (C)(i), by striking
23 “and for amounts” and inserting “and, for a
24 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”.

9 (c) MANUFACTURER DISCOUNT PROGRAM.—

14. "SEC. 1860D-14B. MANUFACTURER DISCOUNT PROGRAM.

15 “(a) ESTABLISHMENT.—The Secretary shall estab-
16 lish a manufacturer discount program (in this section re-
17 ferred to as the ‘program’). Under the program, the Sec-
18 retary shall enter into agreements described in subsection
19 (b) with manufacturers and provide for the performance
20 of the duties described in subsection (c). The Secretary
21 shall establish a model agreement for use under the pro-
22 gram by not later than January 1, 2021, in consultation
23 with manufacturers, and allow for comment on such model
24 agreement.

25 "(b) TERMS OF AGREEMENT.—

1 “(1) IN GENERAL.—

2 “(A) AGREEMENT.—An agreement under
3 this section shall require the manufacturer to
4 provide applicable beneficiaries access to dis-
5 counted prices for applicable drugs of the man-
6 ufacturer that are dispensed on or after Janu-
7 ary 1, 2022.

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

14 “(C) TIMING OF AGREEMENT.—

15 “(i) SPECIAL RULE FOR 2022.—In
16 order for an agreement with a manufac-
17 turer to be in effect under this section with
18 respect to the period beginning on January
19 1, 2022, and ending on December 31,
20 2022, the manufacturer shall enter into
21 such agreement not later than 30 days
22 after the date of the establishment of a
23 model agreement under subsection (a).

24 “(ii) 2023 AND SUBSEQUENT
25 YEARS.—In order for an agreement with a

1 manufacturer to be in effect under this
2 section with respect to plan year 2023 or
3 a subsequent plan year, the manufacturer
4 shall enter into such agreement (or such
5 agreement shall be renewed under para-
6 graph (4)(A)) not later than January 30 of
7 the preceding year.

8 “(2) PROVISION OF APPROPRIATE DATA.—Each
9 manufacturer with an agreement in effect under this
10 section shall collect and have available appropriate
11 data, as determined by the Secretary, to ensure that
12 it can demonstrate to the Secretary compliance with
13 the requirements under the program.

14 “(3) COMPLIANCE WITH REQUIREMENTS FOR
15 ADMINISTRATION OF PROGRAM.—Each manufac-
16 turer with an agreement in effect under this section
17 shall comply with requirements imposed by the Sec-
18 retary or a third party with a contract under sub-
19 section (d)(3), as applicable, for purposes of admin-
20 istering the program, including any determination
21 under subparagraph (A) of subsection (c)(1) or pro-
22 cedures established under such subsection (c)(1).

23 “(4) LENGTH OF AGREEMENT.—

24 “(A) IN GENERAL.—An agreement under
25 this section shall be effective for an initial pe-

1 riod of not less than 12 months and shall be
2 automatically renewed for a period of not less
3 than 1 year unless terminated under subpara-
4 graph (B).

5 “(B) TERMINATION.—

6 “(i) BY THE SECRETARY.—The Sec-
7 retary may provide for termination of an
8 agreement under this section for a knowing
9 and willful violation of the requirements of
10 the agreement or other good cause shown.
11 Such termination shall not be effective ear-
12 lier than 30 days after the date of notice
13 to the manufacturer of such termination.
14 The Secretary shall provide, upon request,
15 a manufacturer with a hearing concerning
16 such a termination, and such hearing shall
17 take place prior to the effective date of the
18 termination with sufficient time for such
19 effective date to be repealed if the Sec-
20 retary determines appropriate.

21 “(ii) BY A MANUFACTURER.—A man-
22 ufacturer may terminate an agreement
23 under this section for any reason. Any
24 such termination shall be effective, with re-
25 spect to a plan year—

1 “(I) if the termination occurs be-
2 fore January 30 of a plan year, as of
3 the day after the end of the plan year;
4 and

5 “(II) if the termination occurs on
6 or after January 30 of a plan year, as
7 of the day after the end of the suc-
8 ceeding plan year.

9 “(iii) EFFECTIVENESS OF TERMI-
10 NATION.—Any termination under this sub-
11 paragraph shall not affect discounts for
12 applicable drugs of the manufacturer that
13 are due under the agreement before the ef-
14 fective date of its termination.

15 “(iv) NOTICE TO THIRD PARTY.—The
16 Secretary shall provide notice of such ter-
17 mination to a third party with a contract
18 under subsection (d)(3) within not less
19 than 30 days before the effective date of
20 such termination.

21 “(c) DUTIES DESCRIBED.—The duties described in
22 this subsection are the following:

23 “(1) ADMINISTRATION OF PROGRAM.—Admin-
24 istering the program, including—

1 “(A) the determination of the amount of
2 the discounted price of an applicable drug of a
3 manufacturer;

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

9 “(C) the establishment of procedures to
10 ensure that, not later than the applicable num-
11 ber of calendar days after the dispensing of an
12 applicable drug by a pharmacy or mail order
13 service, the pharmacy or mail order service is
14 reimbursed for an amount equal to the dif-
15 ference between—

16 “(i) the negotiated price of the appli-
17 cable drug; and

18 “(ii) the discounted price of the appli-
19 cable drug;

20 “(D) the establishment of procedures to
21 ensure that the discounted price for an applica-
22 ble drug under this section is applied before any
23 coverage or financial assistance under other
24 health benefit plans or programs that provide
25 coverage or financial assistance for the pur-

1 chase or provision of prescription drug coverage
2 on behalf of applicable beneficiaries as the Sec-
3 retary may specify; and

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

9 “(2) MONITORING COMPLIANCE.—

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

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

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

25 “(d) ADMINISTRATION.—

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

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

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

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

20 “(B) receive, distribute, or facilitate the
21 distribution of funds of manufacturers to ap-
22 propriate individuals or entities in order to
23 meet the obligations of manufacturers under
24 agreements under this section;

1 “(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

6 “(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.

11 “(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.

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

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

23 “(e) ENFORCEMENT.—

1 “(1) AUDITS.—Each manufacturer with an
2 agreement in effect under this section shall be sub-
3 ject to periodic audit by the Secretary.

4 “(2) CIVIL MONEY PENALTY.—

5 “(A) IN GENERAL.—The Secretary may
6 impose a civil money penalty on a manufacturer
7 that fails to provide applicable beneficiaries dis-
8 counts for applicable drugs of the manufacturer
9 in accordance with such agreement for each
10 such failure in an amount the Secretary deter-
11 mines is commensurate with the sum of—

12 “(i) the amount that the manufac-
13 turer would have paid with respect to such
14 discounts under the agreement, which will
15 then be used to pay the discounts which
16 the manufacturer had failed to provide;
17 and

18 “(ii) 25 percent of such amount.

19 “(B) APPLICATION.—The provisions of
20 section 1128A (other than subsections (a) and
21 (b)) shall apply to a civil money penalty under
22 this paragraph in the same manner as such
23 provisions apply to a penalty or proceeding
24 under section 1128A(a).

1 “(f) CLARIFICATION REGARDING AVAILABILITY OF
2 OTHER COVERED PART D DRUGS.—Nothing in this sec-
3 tion shall prevent an applicable beneficiary from pur-
4 chasing a covered part D drug that is not an applicable
5 drug (including a generic drug or a drug that is not on
6 the formulary of the prescription drug plan or MA–PD
7 plan that the applicable beneficiary is enrolled in).

8 “(g) DEFINITIONS.—In this section:

9 “(1) APPLICABLE BENEFICIARY.—The term
10 ‘applicable beneficiary’ means an individual who, on
11 the date of dispensing a covered part D drug—

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

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

16 “(C) has incurred costs for covered part D
17 drugs in the year that are equal to or exceed
18 the annual deductible specified in section
19 1860D–2(b)(1) for such year.

20 “(2) APPLICABLE DRUG.—The term ‘applicable
21 drug’, with respect to an applicable beneficiary
22 means a covered part D drug—

23 “(A) approved under a new drug applica-
24 tion under section 505(b) of the Federal Food,
25 Drug, and Cosmetic Act or, in the case of a bio-

1 logic product, licensed under section 351 of the
2 Public Health Service Act; and

3 “(B)(i) if the PDP sponsor of the prescrip-
4 tion drug plan or the MA organization offering
5 the MA–PD plan uses a formulary, which is on
6 the formulary of the prescription drug plan or
7 MA–PD plan that the applicable beneficiary is
8 enrolled in;

9 “(ii) if the PDP sponsor of the prescrip-
10 tion drug plan or the MA organization offering
11 the MA–PD plan does not use a formulary, for
12 which benefits are available under the prescrip-
13 tion drug plan or MA–PD plan that the appli-
14 cable beneficiary is enrolled in; or

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

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

20 “(A) with respect to claims for reimburse-
21 ment submitted electronically, 14 days; and

22 “(B) with respect to claims for reimburse-
23 ment submitted otherwise, 30 days.

24 “(4) DISCOUNTED PRICE.—

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

5 “(i) who has not incurred costs for
6 covered part D drugs in the year that are
7 equal to or exceed the annual out-of-pocket
8 threshold specified in section 1860D–
9 2(b)(4)(B)(i) for the year, 90 percent of
10 the negotiated price of such drug; and

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

15 “(B) CLARIFICATION.—Nothing in this
16 section shall be construed as affecting the re-
17 sponsibility of an applicable beneficiary for pay-
18 ment of a dispensing fee for an applicable drug.

19 “(C) SPECIAL CASE FOR CERTAIN
20 CLAIMS.—

21 “(i) CLAIMS SPANNING DEDUCT-
22 IBLE.—In the case where the entire
23 amount of the negotiated price of an indi-
24 vidual claim for an applicable drug with re-
25 spect to an applicable beneficiary does not

1 fall at or above the annual deductible spec-
2 ified in section 1860D-2(b)(1) for the
3 year, the manufacturer of the applicable
4 drug shall provide the discounted price
5 under this section on only the portion of
6 the negotiated price of the applicable drug
7 that falls at or above such annual deduct-
8 ible.

9 “(ii) CLAIMS SPANNING OUT-OF-POCK-
10 ET THRESHOLD.—In the case where the
11 entire amount of the negotiated price of an
12 individual claim for an applicable drug
13 with respect to an applicable beneficiary
14 does not fall entirely below or entirely
15 above the annual out-of-pocket threshold
16 specified in section 1860D-2(b)(4)(B)(i)
17 for the year, the manufacturer of the ap-
18 plicable drug shall provide the discounted
19 price—

20 “(I) in accordance with subpara-
21 graph (A)(i) on the portion of the ne-
22 gotiated price of the applicable drug
23 that falls below such threshold; and
24 “(II) in accordance with subpara-
25 graph (A)(ii) on the portion of such

1 price of such drug that falls at or
2 above such threshold.

3 “(5) MANUFACTURER.—The term ‘manufac-
4 turer’ means any entity which is engaged in the pro-
5 duction, preparation, propagation, compounding,
6 conversion, or processing of prescription drug prod-
7 ucts, either directly or indirectly by extraction from
8 substances of natural origin, or independently by
9 means of chemical synthesis, or by a combination of
10 extraction and chemical synthesis. Such term does
11 not include a wholesale distributor of drugs or a re-
12 tail pharmacy licensed under State law.

13 “(6) NEGOTIATED PRICE.—The term ‘nego-
14 tiated price’ has the meaning given such term in sec-
15 tion 423.100 of title 42, Code of Federal Regula-
16 tions (as in effect on the date of enactment of sec-
17 tion 1860D–14A), except that such negotiated price
18 shall not include any dispensing fee for the applica-
19 ble drug.

20 “(7) QUALIFIED RETIREE PRESCRIPTION DRUG
21 PLAN.—The term ‘qualified retiree prescription drug
22 plan’ has the meaning given such term in section
23 1860D-22(a)(2).”.

24 (2) SUNSET OF MEDICARE COVERAGE GAP DIS-
25 COUNT PROGRAM—Section 1860D-14A of the So-

1 cial Security Act (42 U.S.C. 1395–114a) is amend-
2 ed—

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

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

8 “(h) SUNSET OF PROGRAM.—

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

14 “(2) CONTINUED APPLICATION FOR APPLICA-
15 BLE DRUGS DISPENSED PRIOR TO SUNSET.—The
16 provisions of this section (including all responsibil-
17 ties and duties) shall continue to apply after Janu-
18 ary 1, 2022, with respect to applicable drugs dis-
19 pensed prior to such date.”.

20 “(3) INCLUSION OF ACTUARIAL VALUE OF MANU-
21 FACTURER DISCOUNTS IN BIDS.—Section 1860D–11
22 of the Social Security Act (42 U.S.C. 1395w–111)
23 is amended—

24 (A) in subsection (b)(2)(C)(iii)—

4 “(I) the reinsurance”; and

(ii) by adding at the end the following:

12 (B) in subsection (c)(1)(C)—

“(i) the reinsurance”;

20 (iii) by adding at the end the fol-
21 lowing:

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

25 (d) CONFORMING AMENDMENTS.—

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

7 (B) in subsection (c)(1)(C)—

1 (A) in paragraph (1)—
2 (i) in subparagraph (C), by striking
3 “The continuation” and inserting “For a
4 year preceding 2022, the continuation”;
5 (ii) in subparagraph (D)(iii), by strik-
6 ing “1860D–2(b)(4)(A)(i)(I)” and insert-
7 ing “1860D–2(b)(4)(A)(i)(I)(aa)”; and
8 (iii) in subparagraph (E), by striking
9 “The elimination” and inserting “For a
10 year preceding 2022, the elimination”; and
11 (B) in paragraph (2)—
12 (i) in subparagraph (C), by striking
13 “The continuation” and inserting “For a
14 year preceding 2022, the continuation”;
15 and
16 (ii) in subparagraph (E)—
17 (I) by inserting “for a year pre-
18 ceding 2022,” after “subsection (c)”;
19 and
20 (II) by striking “1860D–
21 2(b)(4)(A)(i)(I)” and inserting
22 “1860D–2(b)(4)(A)(i)(I)(aa)”.
23 (4) Section 1860D–21(d)(7) of the Social Secu-
24 rity Act (42 U.S.C. 1395w–131(d)(7)) is amended

1 by striking “section 1860D–2(b)(4)(B)(i)” and inserting “section 1860D–2(b)(4)(C)(i)”.

3 (5) Section 1860D–22(a)(2)(A) of the Social
4 Security Act (42 U.S.C. 1395w–132(a)(2)(A)) is
5 amended—

6 (A) by striking “the value of any discount”
7 and inserting the following: “the value of—
8 “(i) for years prior to 2022, any dis-
9 count”;

10 (B) in clause (i), as inserted by subpara-
11 graph (A) of this paragraph, by striking the pe-
12 riod at the end and inserting “; and”; and

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

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

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

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

22 (B) by inserting “for such year” before the
23 period.

1 (7) Paragraph (1) of section 1860D–43(a) of
2 the Social Security Act (42 U.S.C. 1395w–153(a)) is
3 amended to read as follows:

4 “(1) participate in—

5 “(A) for 2011 through 2021, the Medicare
6 coverage gap discount program under section
7 1860D–14A; and

8 “(B) for 2022 and each subsequent year,
9 the manufacturer discount program under sec-
10 tion 1860D–14B;”.

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

