

117TH CONGRESS
1ST SESSION

S. 2327

To amend title XVIII of the Social Security Act to provide for a Medicare part D modernization redesign and to establish a monthly out-of-pocket cost sharing maximum for enrollees who incur a significant portion of costs towards the annual out-of-pocket threshold under Medicare part D.

IN THE SENATE OF THE UNITED STATES

JULY 13, 2021

Mr. CASSIDY (for himself and Mr. MENENDEZ) introduced the following bill;
which was read twice and referred to the Committee on Finance

A BILL

To amend title XVIII of the Social Security Act to provide for a Medicare part D modernization redesign and to establish a monthly out-of-pocket cost sharing maximum for enrollees who incur a significant portion of costs towards the annual out-of-pocket threshold under Medicare part D.

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 “Seniors Prescription
5 Drug Relief Act”.

1 **SEC. 2. MEDICARE PART D MODERNIZATION 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 2024 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 2024 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 2024,” after “paragraph
17 (4),”; and

18 (ii) in clause (ii)(III), by striking
19 “and each subsequent year” and inserting
20 “, 2021, 2022, and 2023”; 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 2024,” after “paragraph
26 (4),”; and

1 (II) in subclause (I)(bb), by
 2 striking “a year after 2018” and in-
 3 serting “each of years 2018 through
 4 2023”; and

5 (ii) in clause (ii)(V), by striking
 6 “2019 and each subsequent year” and in-
 7 serting “each of years 2019 through
 8 2023”;

9 (2) in paragraph (3)(A)—

10 (A) in the matter preceding clause (i), by
 11 inserting “for a year preceding 2024,” after
 12 “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 2023”;

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 indenting appro-
 22 priately;

23 (II) in the matter preceding item
 24 (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 2024,
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 2024 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)”;

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 2023 for purposes of
22 section 1860D–14(a)(1)(D)(iii).”;

23 (B) in subparagraph (B)—

24 (i) in clause (i)—

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

3 (II) in subclause (VI)—

4 (aa) by striking “for a sub-
5 sequent year” and inserting “for
6 2021, 2022, and 2023”; and

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

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

12 “(VII) for 2024, is equal to
13 \$3,100; or

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

20 (ii) in clause (ii), by striking “clause
21 (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 2024 for amounts”; and

(D) in subparagraph (E), by striking “In applying” and inserting “For each of 2011 through 2023, in applying”.

(b) REDUCTION IN BENEFICIARY COINSURANCE.—

(1) IN GENERAL.—Section 1860D–2(b)(2)(A) of the Social Security Act (42 U.S.C. 1395w–102(b)(2)(A)), as amended by subsection (a), is amended—

(A) by redesignating clauses (i) and (ii) as subclauses (I) and (II) and moving such subclauses 2 ems to the right;

(B) by striking “25 PERCENT COINSURANCE.—Subject to” and inserting “COINSURANCE.—

“(i) IN GENERAL.—Subject to”;

(C) in each of subclauses (I) and (II), as redesignated by subparagraph (A), by striking “25 percent” and inserting “the applicable percentage (as defined in clause (ii))”; and

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

“(ii) APPLICABLE PERCENTAGE DEFINED.—For purposes of clause (i), the term ‘applicable percentage’ means—

1 “(I) for a year preceding 2024,
2 25 percent; and

3 “(II) for 2024 and each subse-
4 quent year, 20 percent.”.

5 (2) CONFORMING AMENDMENT.—Section
6 1860D–14(a)(2)(D) of the Social Security Act (42
7 U.S.C. 1395w–114(a)(2)(D)) is amended by striking
8 “25 percent” and inserting “the applicable percent-
9 age”.

10 (c) DECREASING REINSURANCE PAYMENT
11 AMOUNT.—Section 1860D–15(b) of the Social Security
12 Act (42 U.S.C. 1395w–115(b)) is amended—

13 (1) in paragraph (1)—

14 (A) by striking “equal to 80 percent” and
15 inserting “equal to—

16 “(A) for a year preceding 2024, 80 per-
17 cent”;

18 (B) in subparagraph (A), as added by
19 paragraph (1), by striking the period at the end
20 and inserting “; and”; and

21 (C) by adding at the end the following new
22 subparagraph:

23 “(B) for 2024 and each subsequent year,
24 the sum of—

1 “(i) an amount equal to the applicable
2 percentage specified in paragraph (5)(A) of
3 such allowable reinsurance costs attrib-
4 utable to that portion of gross prescription
5 drug costs as specified in paragraph (3) in-
6 curred in the coverage year after such indi-
7 vidual has incurred costs that exceed the
8 annual out-of-pocket threshold specified in
9 section 1860D–2(b)(4)(B) with respect to
10 applicable drugs (as defined in section
11 1860D–14B(g)(2)); and

12 “(ii) an amount equal to the applica-
13 ble percentage specified in paragraph
14 (5)(B) of allowable reinsurance costs at-
15 tributable to that portion of gross prescrip-
16 tion drug costs as specified in paragraph
17 (3) incurred in the coverage year after
18 such individual has incurred costs that ex-
19 ceed the annual out-of-pocket threshold
20 specified in section 1860D–2(b)(4)(B) with
21 respect to covered part D drugs that are
22 not applicable drugs (as so defined).”; and

23 (2) by adding at the end the following new
24 paragraph:

1 “(5) APPLICABLE PERCENTAGE SPECIFIED.—

2 For purposes of paragraph (1)(B), the applicable
3 percentage specified in this paragraph is—

4 “(A) with respect to applicable drugs (as
5 defined in section 1860D–14B(g)(2))—

6 “(i) for 2024, 60 percent;

7 “(ii) for 2025, 40 percent; and

8 “(iii) for 2026 and each subsequent
9 year, 20 percent; and

10 “(B) with respect to covered part D drugs
11 that are not applicable drugs (as so defined)—

12 “(i) for 2024, 80 percent;

13 “(ii) for 2025, 60 percent; and

14 “(iii) for 2026 and each subsequent
15 year, 40 percent.”.

16 (d) MANUFACTURER DISCOUNT PROGRAM DURING
17 INITIAL AND CATASTROPHIC PHASES OF COVERAGE.—

18 (1) IN GENERAL.—Part D of title XVIII of the
19 Social Security Act is amended by inserting after
20 section 1860D–14A (42 U.S.C. 1495w–114) the fol-
21 lowing new section:

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

23 “(a) ESTABLISHMENT.—The Secretary shall estab-
24 lish a manufacturer discount program (in this section re-
25 ferred to as the ‘program’). Under the program, the Sec-

1 retary shall enter into agreements described in subsection
 2 (b) with manufacturers and provide for the performance
 3 of the duties described in subsection (c). The Secretary
 4 shall establish a model agreement for use under the pro-
 5 gram by not later than January 1, 2023, in consultation
 6 with manufacturers, and allow for comment on such model
 7 agreement.

8 “(b) TERMS OF AGREEMENT.—

9 “(1) IN GENERAL.—

10 “(A) AGREEMENT.—An agreement under
 11 this section shall require the manufacturer to
 12 provide applicable beneficiaries access to dis-
 13 counted prices for applicable drugs of the man-
 14 ufacturer that are dispensed on or after Janu-
 15 ary 1, 2024.

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

22 “(2) PROVISION OF APPROPRIATE DATA.—Each
 23 manufacturer with an agreement in effect under this
 24 section shall collect and have available appropriate
 25 data, as determined by the Secretary, to ensure that

1 it can demonstrate to the Secretary compliance with
2 the requirements under the program.

3 “(3) COMPLIANCE WITH REQUIREMENTS FOR
4 ADMINISTRATION OF PROGRAM.—Each manufac-
5 turer with an agreement in effect under this section
6 shall comply with requirements imposed by the Sec-
7 retary or a third party with a contract under sub-
8 section (d)(3), as applicable, for purposes of admin-
9 istering the program, including any determination
10 under subparagraph (A) of subsection (c)(1) or pro-
11 cedures established under such subsection (c)(1).

12 “(4) LENGTH OF AGREEMENT.—

13 “(A) IN GENERAL.—An agreement under
14 this section shall be effective for an initial pe-
15 riod of not less than 12 months and shall be
16 automatically renewed for a period of not less
17 than 1 year unless terminated under subpara-
18 graph (B).

19 “(B) TERMINATION.—

20 “(i) BY THE SECRETARY.—The Sec-
21 retary may provide for termination of an
22 agreement under this section for a knowing
23 and willful violation of the requirements of
24 the agreement or other good cause shown.
25 Such termination shall not be effective ear-

1 lier than 30 days after the date of notice
2 to the manufacturer of such termination.
3 The Secretary shall provide, upon request,
4 a manufacturer with a hearing concerning
5 such a termination, and such hearing shall
6 take place prior to the effective date of the
7 termination with sufficient time for such
8 effective date to be repealed if the Sec-
9 retary determines appropriate.

10 “(ii) BY A MANUFACTURER.—A man-
11 ufacturer may terminate an agreement
12 under this section for any reason. Any
13 such termination shall be effective, with re-
14 spect to a plan year—

15 “(I) if the termination occurs be-
16 fore January 30 of a plan year, as of
17 the day after the end of the plan year;
18 and

19 “(II) if the termination occurs on
20 or after January 30 of a plan year, as
21 of the day after the end of the suc-
22 ceeding plan year.

23 “(iii) EFFECTIVENESS OF TERMI-
24 NATION.—Any termination under this sub-
25 paragraph shall not affect discounts for

1 applicable drugs of the manufacturer that
2 are due under the agreement before the ef-
3 fective date of its termination.

4 “(iv) NOTICE TO THIRD PARTY.—The
5 Secretary shall provide notice of such ter-
6 mination to a third party with a contract
7 under subsection (d)(3) within not less
8 than 30 days before the effective date of
9 such termination.

10 “(5) EFFECTIVE DATE OF AGREEMENT.—An
11 agreement under this section shall take effect on a
12 date determined appropriate by the Secretary, which
13 may be at the start of a calendar quarter.

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

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

18 “(A) the determination of the amount of
19 the discounted price of an applicable drug of a
20 manufacturer;

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

1 “(C) the establishment of procedures to
2 ensure that, not later than the applicable num-
3 ber of calendar days after the dispensing of an
4 applicable drug by a pharmacy or mail order
5 service, the pharmacy or mail order service is
6 reimbursed for an amount equal to the dif-
7 ference between—

8 “(i) the negotiated price of the appli-
9 cable drug; and

10 “(ii) the discounted price of the appli-
11 cable drug;

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

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

1 “(2) MONITORING COMPLIANCE.—

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

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

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

17 “(d) ADMINISTRATION.—

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

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

1 “(3) CONTRACT WITH THIRD PARTIES.—The
2 Secretary shall enter into a contract with 1 or more
3 third parties to administer the requirements estab-
4 lished by the Secretary in order to carry out this
5 section. At a minimum, the contract with a third
6 party under the preceding sentence shall require
7 that the third party—

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

12 “(B) receive, distribute, or facilitate the
13 distribution of funds of manufacturers to ap-
14 propriate individuals or entities in order to
15 meet the obligations of manufacturers under
16 agreements under this section;

17 “(C) provide adequate and timely informa-
18 tion to manufacturers, consistent with the
19 agreement with the manufacturer under this
20 section, as necessary for the manufacturer to
21 fulfill its obligations under this section; and

22 “(D) permit manufacturers to conduct
23 periodic audits, directly or through contracts, of
24 the data and information used by the third

1 party to determine discounts for applicable
2 drugs of the manufacturer under the program.

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

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

12 “(6) FUNDING.—For purposes of carrying out
13 this section, the Secretary shall provide for the
14 transfer, from the Federal Supplementary Medical
15 Insurance Trust Fund under section 1841 to the
16 Centers for Medicare & Medicaid Services Program
17 Management Account, of \$4,000,000 for each of fis-
18 cal years 2021 through 2024, to remain available
19 until expended.”.

20 “(e) ENFORCEMENT.—

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

24 “(2) CIVIL MONEY PENALTY.—

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

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

14 “(ii) 25 percent of such amount.

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

21 “(f) CLARIFICATION REGARDING AVAILABILITY OF
 22 OTHER COVERED PART D DRUGS.—Nothing in this sec-
 23 tion shall prevent an applicable beneficiary from pur-
 24 chasing a covered part D drug that is not an applicable
 25 drug (including a generic drug or a drug that is not on

1 the formulary of the prescription drug plan or MA–PD
 2 plan that the applicable beneficiary is enrolled in).

3 “(g) DEFINITIONS.—In this section:

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

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

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

11 “(C) has incurred costs for covered part D
 12 drugs in the year that are above the annual de-
 13 ductible specified in section 1860D–2(b)(1) for
 14 such year.

15 “(2) APPLICABLE DRUG.—The term ‘applicable
 16 drug’ means, with respect to an applicable bene-
 17 ficiary, a covered part D drug—

18 “(A) approved under a new drug applica-
 19 tion under section 505(c) of the Federal Food,
 20 Drug, and Cosmetic Act or, in the case of a bio-
 21 logic product, licensed under section 351 of the
 22 Public Health Service Act (including a product
 23 licensed under subsection (k) of such section
 24 351); and

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

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

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

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

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

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

22 “(4) DISCOUNTED PRICE.—

23 “(A) IN GENERAL.—Except as provided in
 24 subparagraph (B), the term ‘discounted price’

1 means 90 percent of the negotiated price of the
 2 applicable drug of a manufacturer.

3 “(B) PHASE-IN FOR CERTAIN DRUGS DIS-
 4 PENSED FOR SUBSIDY ELIGIBLE INDIVID-
 5 UALS.—

6 “(i) IN GENERAL.—In the case of an
 7 applicable drug of a specified manufacturer
 8 (as defined in clause (ii)) that is dispensed
 9 for an applicable beneficiary who is a sub-
 10 sidy eligible individual (as defined in sec-
 11 tion 1860D–14(a)(3)), the term ‘dis-
 12 counted price’ means the specified LIS
 13 percent (as defined in clause (iii)) of the
 14 negotiated price of the applicable drug of
 15 the manufacturer.

16 “(ii) SPECIFIED MANUFACTURER.—In
 17 this subparagraph, the term ‘specified
 18 manufacturer’ means a manufacturer of an
 19 applicable drug for which, in the calendar
 20 year 2 years prior to the current plan year
 21 (referred to in this clause as the ‘applicable
 22 period’), the total reimbursement under
 23 this title during the applicable period rep-
 24 resented less than 1 percent of the total re-

1 imbursement under this title for all pre-
2 scription drugs during such period.

3 “(iii) SPECIFIED LIS PERCENT.—In
4 this subparagraph, the term ‘specified LIS
5 percent’ means—

6 “(I) for 2024, 98 percent;

7 “(II) for 2025, 97 percent;

8 “(III) for 2026, 96 percent;

9 “(IV) for 2027, 95 percent;

10 “(V) for 2028, 94 percent;

11 “(VI) for 2029, 93 percent;

12 “(VII) for 2030, 92 percent;

13 “(VIII) for 2031, 91 percent;

14 and

15 “(IX) for 2032 and each subse-
16 quent year, 90 percent.

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

21 “(5) MANUFACTURER.—The term ‘manufac-
22 turer’ means any entity which is engaged in the pro-
23 duction, preparation, propagation, compounding,
24 conversion, or processing of prescription drug prod-
25 ucts, 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 1860D–2(d)(1)(B), 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 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 “(1) IN GENERAL.—The program shall not
 2 apply to applicable drugs dispensed on or after Jan-
 3 uary 1, 2024, and, subject to paragraph (2), agree-
 4 ments under this section shall be terminated as of
 5 such date.

6 “(2) CONTINUED APPLICATION FOR APPLICA-
 7 BLE DRUGS DISPENSED PRIOR TO SUNSET.—The
 8 provisions of this section (including all responsibil-
 9 ities and duties) shall continue to apply after Janu-
 10 ary 1, 2024, with respect to applicable drugs dis-
 11 pensed prior to such date.”.

12 (3) INCLUSION OF ACTUARIAL VALUE OF MANU-
 13 FACTURER DISCOUNTS IN BIDS.—Section 1860D–11
 14 of the Social Security Act (42 U.S.C. 1395w–111)
 15 is amended—

16 (A) in subsection (b)(2)(C)(iii)—

17 (i) by striking “assumptions regarding
 18 the reinsurance” and inserting “assump-
 19 tions regarding—

20 “(I) the reinsurance”; and

21 (ii) by adding at the end the fol-
 22 lowing:

23 “(II) for 2024 and each subse-
 24 quent year, the manufacturer dis-
 25 counts provided under section 1860D–

1 14B subtracted from the actuarial
2 value to produce such bid; and”; and

3 (B) in subsection (c)(1)(C)—

4 (i) by striking “an actuarial valuation
5 of the reinsurance” and inserting “an ac-
6 tuarial valuation of—

7 “(i) the reinsurance”;

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

11 (iii) by adding at the end the fol-
12 lowing:

13 “(ii) for 2024 and each subsequent
14 year, the manufacturer discounts provided
15 under section 1860D–14B;”.

16 (4) CLARIFICATION REGARDING EXCLUSION OF
17 MANUFACTURER DISCOUNTS FROM TROOP.—Section
18 1860D–2(b)(4) of the Social Security Act (42
19 U.S.C. 1395w–102(b)(4)) is amended—

20 (A) in subparagraph (C), by inserting “and
21 subject to subparagraph (F)” after “subpara-
22 graph (E)”;

23 (B) by adding at the end the following new
24 subparagraph:

1 “(F) CLARIFICATION REGARDING EXCLU-
 2 SION OF MANUFACTURER DISCOUNTS.—In ap-
 3 plying subparagraph (A), incurred costs shall
 4 not include any manufacturer discounts pro-
 5 vided under section 1860D–14B.”.

6 (e) DETERMINATION OF ALLOWABLE REINSURANCE
 7 COSTS.—Section 1860D–15(b) of the Social Security Act
 8 (42 U.S.C. 1395w–115(b)) is amended—

9 (1) in paragraph (2)—

10 (A) by striking “COSTS.—For purposes”
 11 and inserting “COSTS.—

12 “(A) IN GENERAL.—Subject to subpara-
 13 graph (B), for purposes”; and

14 (B) by adding at the end the following new
 15 subparagraph:

16 “(B) INCLUSION OF MANUFACTURER DIS-
 17 COUNTS ON APPLICABLE DRUGS.—For purposes
 18 of applying subparagraph (A), the term ‘allow-
 19 able reinsurance costs’ shall include the portion
 20 of the negotiated price (as defined in section
 21 1860D–14B(g)(6)) of an applicable drug (as
 22 defined in section 1860D–14B(g)(2)) that was
 23 paid by a manufacturer under the manufacturer
 24 discount program under section 1860D–14B.”;
 25 and

1 (2) in paragraph (3)—

2 (A) in the first sentence, by striking “For
3 purposes” and inserting “Subject to paragraph
4 (2)(B), for purposes”; and

5 (B) in the second sentence, by inserting
6 “or, in the case of an applicable drug, by a
7 manufacturer” after “by the individual or
8 under the plan”.

9 (f) UPDATING RISK ADJUSTMENT METHODOLOGIES
10 TO ACCOUNT FOR PART D MODERNIZATION REDE-
11 SIGN.—Section 1860D–15(c) of the Social Security Act
12 (42 U.S.C. 1395w–115(c)) is amended by adding at the
13 end the following new paragraph:

14 “(3) UPDATING RISK ADJUSTMENT METH-
15 ODOLOGIES TO ACCOUNT FOR PART D MODERNIZA-
16 TION REDESIGN.—The Secretary shall update the
17 risk adjustment methodologies used to adjust bid
18 amounts pursuant to this subsection as appropriate
19 to take into account changes in benefits under this
20 part pursuant to the amendments made by section
21 2 of the Seniors Prescription Drug Relief Act.”.

22 (g) CONDITIONS FOR COVERAGE OF DRUGS UNDER
23 THIS PART.—Section 1860D–43 of the Social Security
24 Act (42 U.S.C. 1395w–153) is amended—

25 (1) in subsection (a)—

1 (A) in paragraph (2), by striking “and” at
2 the end;

3 (B) in paragraph (3), by striking the pe-
4 riod at the end and inserting a semicolon; and

5 (C) by adding at the end the following new
6 paragraphs:

7 “(4) participate in the manufacturer discount
8 program under section 1860D–14B;

9 “(5) have entered into and have in effect an
10 agreement described in subsection (b) of such sec-
11 tion 1860D–14B with the Secretary; and

12 “(6) have entered into and have in effect, under
13 terms and conditions specified by the Secretary, a
14 contract with a third party that the Secretary has
15 entered into a contract with under subsection (d)(3)
16 of such section 1860D–14B.”;

17 (2) by striking subsection (b) and inserting the
18 following:

19 “(b) EFFECTIVE DATE.—Paragraphs (1) through (3)
20 of subsection (a) shall apply to covered part D drugs dis-
21 pensed under this part on or after January 1, 2011, and
22 before January 1, 2024, and paragraphs (4) through (6)
23 of such subsection shall apply to covered part D drugs
24 dispensed on or after January 1, 2024.”; and

1 (3) in subsection (c), by striking paragraph (2)
2 and inserting the following:

3 “(2) the Secretary determines that in the period
4 beginning on January 1, 2011, and ending on De-
5 cember 31, 2011 (with respect to paragraphs (1)
6 through (3) of subsection (a)), or the period begin-
7 ning on January 1, 2024, and ending December 31,
8 2024 (with respect to paragraphs (4) through (6) of
9 such subsection), there were extenuating cir-
10 cumstances.”.

11 (h) CONFORMING AMENDMENTS.—

12 (1) Section 1860D–2 of the Social Security Act
13 (42 U.S.C. 1395w–102) is amended—

14 (A) in subsection (a)(2)(A)(i)(I), by strik-
15 ing “, or an increase in the initial” and insert-
16 ing “or for a year preceding 2024 an increase
17 in the initial”;

18 (B) in subsection (c)(1)(C)—

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

22 (ii) by inserting “for a year preceding
23 2024 or the annual out-of-pocket threshold
24 specified in subsection (b)(4)(B) for the
25 year for 2024 and each subsequent year”

1 after “subsection (b)(3) for the year” each
 2 place it appears; and

3 (C) in subsection (d)(1)(A), by striking “or
 4 an initial” and inserting “or for a year pre-
 5 ceding 2024 an initial”.

6 (2) Section 1860D–4(a)(4)(B)(i) of the Social
 7 Security Act (42 U.S.C. 1395w–104(a)(4)(B)(i)) is
 8 amended by striking “the initial” and inserting “for
 9 a year preceding 2024, the initial”.

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

12 (A) in paragraph (1)—

13 (i) in subparagraph (C), by striking
 14 “The continuation” and inserting “For a
 15 year preceding 2024, the continuation”;

16 (ii) in subparagraph (D)(iii), by strik-
 17 ing “1860D–2(b)(4)(A)(i)(I)” and insert-
 18 ing “1860D–2(b)(4)(A)(i)(I)(aa)”; and

19 (iii) in subparagraph (E), by striking
 20 “The elimination” and inserting “For a
 21 year preceding 2024, the elimination”; and

22 (B) in paragraph (2)—

23 (i) in subparagraph (C), by striking
 24 “The continuation” and inserting “For a

1 year preceding 2024, the continuation”;
2 and

3 (ii) in subparagraph (E)—

4 (I) by inserting “for a year pre-
5 ceding 2024,” after “subsection (c)”;
6 and

7 (II) by striking “1860D-
8 2(b)(4)(A)(i)(I)” and inserting
9 “1860D-2(b)(4)(A)(i)(I)(aa)”.

10 (4) Section 1860D-21(d)(7) of the Social Secu-
11 rity Act (42 U.S.C. 1395w-131(d)(7)) is amended
12 by striking “section 1860D-2(b)(B)(4)(B)(i)” and
13 inserting “section 1860D-2(b)(B)(4)(C)(i)”.

14 (5) Section 1860D-22(a)(2)(A) of the Social
15 Security Act (42 U.S.C. 1395w-132(a)(2)(A)) is
16 amended—

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

19 “(i) for years prior to 2024, any dis-
20 count”;

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

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

1 “(ii) for 2024 and each subsequent
 2 year, any discount provided pursuant to
 3 section 1860D–14B.”.

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

6 (A) by inserting “for a year before 2024”
 7 after “1860D–2(b)(3)”; and

8 (B) by inserting “for such year” before the
 9 period.

10 (i) EFFECTIVE DATE.—The amendments made by
 11 this section shall apply to plan year 2024 and subsequent
 12 plan years.

13 **SEC. 3. MONTHLY OUT-OF-POCKET COST SHARING MAX-**
 14 **IMUM FOR ENROLLEES WHO INCUR A SIG-**
 15 **NIFICANT PORTION OF COSTS TOWARDS AN-**
 16 **NUAL OUT-OF-POCKET THRESHOLD.**

17 (a) IN GENERAL.—Section 1860D–2(b) of the Social
 18 Security Act (42 U.S.C. 1395w–102(b)), as amended by
 19 section 2, is amended—

20 (1) in paragraph (2)—

21 (A) in subparagraph (A), by striking “and
 22 (D)” and inserting “, (D), and (E)”; and

23 (B) by adding at the end the following new
 24 subparagraph:

1 “(E) MONTHLY OUT-OF-POCKET COST
 2 SHARING MAXIMUM FOR ENROLLEES WHO
 3 INCUR A SIGNIFICANT PORTION OF COSTS TO-
 4 WARDS ANNUAL OUT-OF-POCKET THRESH-
 5 OLD.—

6 “(i) ESTABLISHMENT OF PROCESS.—

7 “(I) IN GENERAL.—For plan
 8 years beginning on or after January
 9 1, 2024, the Secretary shall, through
 10 notice and comment rulemaking, es-
 11 tablish a process under which each
 12 PDP sponsor offering a prescription
 13 drug plan and each MA organization
 14 offering an MA–PD plan shall each
 15 plan year automatically enroll applica-
 16 ble enrollees in the option to have
 17 their monthly out-of-pocket cost-shar-
 18 ing under the plan capped and paid in
 19 monthly installments in accordance
 20 with this subparagraph (referred to in
 21 this subparagraph as the ‘monthly
 22 out-of-pocket cost sharing maximum
 23 option’).

24 “(II) OPT OUT.—The process es-
 25 tablished under this clause shall per-

1 mit an applicable enrollee, prior to the
 2 beginning of the plan year or at any
 3 point during the plan year, to opt out
 4 of enrollment in the monthly out-of-
 5 pocket cost sharing maximum option
 6 and pay any out-of-pocket cost-shar-
 7 ing otherwise applicable for any cov-
 8 ered part D drug in full at the time
 9 of the dispensing of such drug (or at
 10 the time of such opt out in the case
 11 of costs incurred during such enroll-
 12 ment that have not yet been billed to
 13 the enrollee).

14 “(ii) DEFINITIONS.—

15 “(I) APPLICABLE ENROLLEE.—

16 In this subparagraph, the term ‘appli-
 17 cable enrollee’ means any enrollee in a
 18 prescription drug plan or an MA–PD
 19 plan, including an enrollee who is a
 20 subsidy eligible individual (as defined
 21 in paragraph (3) of section 1860D–
 22 14(a)), who incurs or is likely to incur
 23 a significant percentage of costs for
 24 covered part D drugs.

1 “(II) SIGNIFICANT PERCENT-
 2 AGE.—For purposes of subclause (I),
 3 the Secretary shall, in the rulemaking
 4 under clause (i), define the term ‘sig-
 5 nificant percentage’ with respect to a
 6 percentage of the annual out-of-pocket
 7 threshold specified in paragraph
 8 (4)(B) but in no case shall the ‘sig-
 9 nificant percentage’ be less than 50
 10 percent or more than 100 percent of
 11 the annual out-of-pocket threshold.

12 “(iii) DETERMINATION OF MONTHLY
 13 OUT-OF-POCKET COST SHARING MAX-
 14 IMUM.—For each month in a plan year in
 15 which an applicable enrollee is enrolled in
 16 the monthly out-of-pocket cost sharing
 17 maximum option, the PDP sponsor or MA
 18 organization shall determine a monthly
 19 out-of-pocket cost sharing maximum (as
 20 defined in clause (v)) for such enrollee.

21 “(iv) BENEFICIARY MONTHLY PAY-
 22 MENTS.—With respect to an applicable en-
 23 rollee who is enrolled in the monthly out-
 24 of-pocket cost sharing maximum option,
 25 for each month described in clause (iii),

1 the PDP sponsor or MA organization shall
 2 bill such enrollee an amount (not to exceed
 3 the monthly out-of-pocket cost sharing
 4 maximum) for the out-of-pocket costs of
 5 such enrollee in such month.

6 “(v) MONTHLY OUT-OF-POCKET COST
 7 SHARING MAXIMUM DEFINED.—In this
 8 subparagraph, the term ‘monthly out-of-
 9 pocket cost sharing maximum’ means, with
 10 respect to an enrollee—

11 “(I) for the first month in which
 12 this subparagraph applies, an amount
 13 determined by calculating—

14 “(aa) the annual out-of-
 15 pocket threshold specified in
 16 paragraph (4)(B) minus the in-
 17 curred costs of the enrollee as de-
 18 scribed in paragraph (4)(C); di-
 19 vided by

20 “(bb) the number of months
 21 remaining in the plan year; and

22 “(II) for a subsequent month, an
 23 amount determined by calculating—

24 “(aa) the sum of any re-
 25 maining out-of-pocket costs owed

1 by the enrollee from a previous
 2 month that have not yet been
 3 billed to the enrollee and any ad-
 4 ditional costs incurred by the en-
 5 rollee; divided by

6 “(bb) the number of months
 7 remaining in the plan year.

8 “(vi) ADDITIONAL REQUIREMENTS.—
 9 The following requirements shall apply
 10 with respect to the monthly out-of-pocket
 11 cost sharing maximum option under this
 12 subparagraph:

13 “(I) SECRETARIAL RESPONSIBIL-
 14 ITIES.—The Secretary shall provide
 15 information to part D eligible individ-
 16 uals on the monthly out-of-pocket cost
 17 sharing maximum option through edu-
 18 cational materials, including through
 19 the notices provided under section
 20 1804(a).

21 “(II) PDP SPONSOR AND MA OR-
 22 GANIZATION RESPONSIBILITIES.—
 23 Each PDP sponsor offering a pre-
 24 scription drug plan or MA organiza-
 25 tion offering an MA–PD plan—

1 “(aa) shall not limit the ap-
2 plication of the monthly out-of-
3 pocket cost sharing maximum op-
4 tion to certain covered part D
5 drugs;

6 “(bb) shall, prior to the plan
7 year, notify prospective enrollees
8 of such option, including the
9 availability of the opt out under
10 clause (i)(II);

11 “(cc) shall include informa-
12 tion on such option in enrollee
13 educational materials, including
14 the availability of the opt out
15 under clause (i)(II);

16 “(dd) shall have in place a
17 mechanism to notify a pharmacy
18 during the plan year when an en-
19 rollee incurs out-of-pocket costs
20 with respect to covered part D
21 drugs that make it likely the en-
22 rollee is an applicable enrollee;

23 “(ee) shall provide that a
24 pharmacy, after receiving a noti-
25 fication described in item (dd)

1 with respect to an enrollee, in-
2 forms the enrollee of such notifi-
3 cation;

4 “(ff) shall ensure that the
5 application of this subparagraph
6 has no effect on the amount paid
7 to pharmacies (or the timing of
8 such payments) with respect to
9 covered part D drugs dispensed
10 to the enrollee; and

11 “(gg) shall have in place a
12 financial reconciliation process to
13 correct inaccuracies in payments
14 made by an enrollee under this
15 subparagraph with respect to
16 covered part D drugs during the
17 plan year.

18 “(III) FAILURE TO PAY AMOUNT
19 BILLED UNDER MONTHLY OUT-OF-
20 POCKET COST SHARING MAXIMUM OP-
21 TION.—If an applicable enrollee fails
22 to pay the amount billed for a month
23 as required under this subparagraph,
24 the applicable enrollee’s enrollment in
25 the monthly out-of-pocket cost sharing

1 maximum option shall be terminated
 2 and the enrollee shall pay the cost-
 3 sharing otherwise applicable for any
 4 covered part D drugs subsequently
 5 dispensed to the enrollee up to the an-
 6 nual out-of-pocket threshold specified
 7 in paragraph (4)(B).

8 “(IV) CLARIFICATION REGARD-
 9 ING PAST DUE AMOUNTS.—Nothing in
 10 this subparagraph shall be construed
 11 as prohibiting a PDP sponsor or an
 12 MA organization from billing an en-
 13 rollee for an amount owed under this
 14 subparagraph.

15 “(V) TREATMENT OF UNSET-
 16 TLED BALANCES.—Any unsettled bal-
 17 ances with respect to amounts owed
 18 under this subparagraph shall be
 19 treated as plan losses and the Sec-
 20 retary shall not be liable for any such
 21 balances outside of those assumed as
 22 losses estimated in plan bids.”; and

23 (2) in paragraph (4)—

24 (A) in subparagraph (C), by striking “and
 25 subject to subparagraph (F)” and inserting

1 “and subject to subparagraphs (F) and (G”;
 2 and

3 (B) by adding at the end the following new
 4 subparagraph:

5 “(G) INCLUSION OF COSTS PAID UNDER
 6 MONTHLY OUT-OF-POCKET COST SHARING MAX-
 7 IMUM OPTION.—In applying subparagraph (A),
 8 with respect to an applicable enrollee who is en-
 9 rolled in the monthly out-of-pocket cost sharing
 10 maximum option described in clause (i)(I) of
 11 paragraph (2)(E), costs shall be treated as in-
 12 curred if such costs are paid by a PDP sponsor
 13 or an MA organization under the process pro-
 14 vided under such paragraph.”.

15 (b) APPLICATION TO ALTERNATIVE PRESCRIPTION
 16 DRUG COVERAGE.—Section 1860D–2(c) of the Social Se-
 17 curity Act (42 U.S.C. 1395w–102(c)) is amended by add-
 18 ing at the end the following new paragraph:

19 “(4) SAME MONTHLY OUT-OF-POCKET COST
 20 SHARING MAXIMUM.—For plan years beginning on
 21 or after January 1, 2024, the monthly out-of-pocket
 22 cost sharing maximum for applicable enrollees under
 23 the process provided under subsection (b)(2)(E)
 24 shall apply to such coverage.”.

○