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

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

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.

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

SECTION 1. SHORT TITLE.

This Act may be cited as the “Seniors Prescription Drug Relief Act”.

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

(ii) in clause (ii)(III), by striking “and each subsequent year” and inserting “, 2021, 2022, and 2023”; and

(C) in subparagraph (D)—

(i) in clause (i)—

(I) in the matter preceding subclause (I), by inserting “for a year preceding 2024,” after “paragraph (4),”; and
(II) in subclause (I)(bb), by striking “a year after 2018” and inserting “each of years 2018 through 2023”; and

(ii) in clause (ii)(V), by striking “2019 and each subsequent year” and inserting “each of years 2019 through 2023”;

(2) in paragraph (3)(A)—

(A) in the matter preceding clause (i), by inserting “for a year preceding 2024,” after “and (4),”; and

(B) in clause (ii), by striking “for a subsequent year” and inserting “for each of years 2007 through 2023”;

(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 indenting appropriately;

(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 2024,
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 2024 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 2023 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 subsequent year” and inserting “for 2021, 2022, and 2023”; 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 2024, is equal to $3,100; or

“(VIII) for a subsequent year, is equal to the amount specified in this subparagraph for the previous year, increased by the annual percentage increase 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 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—
“(I) for a year preceding 2024,
25 percent; and
“(II) for 2024 and each subse-
quently subsequent year, 20 percent.”.

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

c) DECREASING REINSURANCE PAYMENT
AMOUNT.—Section 1860D–15(b) of the Social Security
Act (42 U.S.C. 1395w–115(b)) is amended—
(1) in paragraph (1)—
(A) by striking “equal to 80 percent” and
inserting “equal to—
“(A) for a year preceding 2024, 80 per-
cent”;
(B) in subparagraph (A), as added by
paragraph (1), by striking the period at the end
and inserting “; and”; and
(C) by adding at the end the following new
subparagraph:
“(B) for 2024 and each subsequent year,
the sum of—
“(i) an amount equal to the applicable percentage specified in paragraph (5)(A) of such allowable reinsurance costs attributable to that portion of gross prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) with respect to applicable drugs (as defined in section 1860D–14B(g)(2)); and

“(ii) an amount equal to the applicable percentage specified in paragraph (5)(B) of allowable reinsurance costs attributable to that portion of gross prescription drug costs as specified in paragraph (3) incurred in the coverage year after such individual has incurred costs that exceed the annual out-of-pocket threshold specified in section 1860D–2(b)(4)(B) with respect to covered part D drugs that are not applicable drugs (as so defined).”;

(2) by adding at the end the following new paragraph:
“(5) APPLICABLE PERCENTAGE SPECIFIED.—
For purposes of paragraph (1)(B), the applicable percentage specified in this paragraph is—

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

“(i) for 2024, 60 percent;
“(ii) for 2025, 40 percent; and
“(iii) for 2026 and each subsequent year, 20 percent; and

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

“(i) for 2024, 80 percent;
“(ii) for 2025, 60 percent; and
“(iii) for 2026 and each subsequent year, 40 percent.”.

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

(1) IN GENERAL.—Part D of title XVIII of the Social Security Act is amended by inserting after section 1860D–14A (42 U.S.C. 1495w–114) 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 Sec-
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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.

“(b) Terms of Agreement.—

“(1) In general.—

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

“(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.

“(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 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 ear-
lier 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.

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

"(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 purchase or provision of prescription drug coverage on behalf of applicable beneficiaries as the Secretary may specify; and

“(E) providing a reasonable dispute resolution mechanism to resolve disagreements between manufacturers, applicable beneficiaries, and the third party with a contract under subsection (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) determines that the manufacturer is not in compliance with such agreement, the third party shall notify the Secretary of such noncompliance for appropriate enforcement under subsection (e).

“(3) Collection of data from prescription drug plans and MA–PD plans.—The Secretary may collect appropriate data from prescription 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 implementation of this section, the Secretary shall not receive or distribute any funds of a manufacturer under the program.
“(3) Contract with third parties.—The Secretary shall enter into a contract with 1 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 require that the third party—

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

“(B) receive, distribute, or facilitate the distribution of funds of manufacturers to appropriate 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) Administration.—Chapter 35 of title 44, United States Code, shall not apply to the program
under this section.

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

“(e) Enforcement.—

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

“(2) Civil money penalty.—
“(A) IN GENERAL.—The Secretary shall 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 above the annual deductible specified in section 1860D–2(b)(1) for such year.

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

“(A) approved under a new drug application under section 505(c) of the Federal Food, Drug, and Cosmetic Act or, in the case of a biologic product, licensed under section 351 of the Public Health Service Act (including a product licensed under subsection (k) of such section 351); 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.—Except as provided in subparagraph (B), the term ‘discounted price’
means 90 percent of the negotiated price of the applicable drug of a manufacturer.

“(B) PHASE-IN FOR CERTAIN DRUGS DISPENSED FOR SUBSIDY ELIGIBLE INDIVIDUALS.—

“(i) IN GENERAL.—In the case of an applicable drug of a specified manufacturer (as defined in clause (ii)) that is dispensed for an applicable beneficiary who is a subsidy eligible individual (as defined in section 1860D–14(a)(3), the term ‘discounted price’ means the specified LIS percent (as defined in clause (iii)) of the negotiated price of the applicable drug of the manufacturer.

“(ii) SPECIFIED MANUFACTURER.—In this subparagraph, the term ‘specified manufacturer’ means a manufacturer of an applicable drug for which, in the calendar year 2 years prior to the current plan year (referred to in this clause as the ‘applicable period’), the total reimbursement under this title during the applicable period represented less than 1 percent of the total re-
imbursement under this title for all prescription drugs during such period.

“(iii) Specified LIS Percent.—In this subparagraph, the term ‘specified LIS percent’ means—

“(I) for 2024, 98 percent;
“(II) for 2025, 97 percent;
“(III) for 2026, 96 percent;
“(IV) for 2027, 95 percent;
“(V) for 2028, 94 percent;
“(VI) for 2029, 93 percent;
“(VII) for 2030, 92 percent;
“(VIII) for 2031, 91 percent;

and

“(IX) for 2032 and each subsequent year, 90 percent.

“(C) 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.

“(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 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) In general.—The program shall not apply to applicable drugs dispensed on or after January 1, 2024, 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, 2024, 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” and inserting “assumptions regarding—

“(I) the reinsurance”; and

(ii) by adding at the end the following:

“(II) for 2024 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 added by clause (i) of this subparagraph, by adding “and” at the end; and
(iii) by adding at the end the following:
“(ii) for 2024 and each subsequent year, the manufacturer discounts provided under section 1860D–14B;
”. (4) Clarification regarding exclusion of manufacturer discounts from TROOP.—Section 1860D–2(b)(4) of the Social Security Act (42 U.S.C. 1395w–102(b)(4)) is amended—
(A) in subparagraph (C), by inserting “and subject to subparagraph (F)” after “subparagraph (E)”); and
(B) by adding at the end the following new subparagraph:
“(F) Clarification regarding exclusion of manufacturer discounts.—In applying subparagraph (A), incurred costs shall not include any manufacturer discounts provided under section 1860D–14B.”.

(e) Determination of allowable reinsurance costs.—Section 1860D–15(b) of the Social Security Act (42 U.S.C. 1395w–115(b)) is amended—

(1) in paragraph (2)—

(A) by striking “costs.—For purposes” and inserting “costs.—

“(A) In general.—Subject to subparagraph (B), for purposes”; and

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

“(B) Inclusion of manufacturer discounts on applicable drugs.—For purposes of applying subparagraph (A), the term ‘allowable reinsurance costs’ shall include the portion of the negotiated price (as defined in section 1860D–14B(g)(6)) of an applicable drug (as defined in section 1860D–14B(g)(2)) that was paid by a manufacturer under the manufacturer discount program under section 1860D–14B.”; and
(2) in paragraph (3)—

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

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

(f) Updating Risk Adjustment Methodologies To Account for Part D Modernization Redesign.—Section 1860D–15(c) of the Social Security Act (42 U.S.C. 1395w–115(c)) is amended by adding at the end the following new paragraph:

“(3) Updating risk adjustment methodologies to account for Part D modernization redesign.—The Secretary shall update the risk adjustment methodologies used to adjust bid amounts pursuant to this subsection as appropriate to take into account changes in benefits under this part pursuant to the amendments made by section 2 of the Seniors Prescription Drug Relief Act.”.

(g) Conditions for Coverage of Drugs Under This Part.—Section 1860D–43 of the Social Security Act (42 U.S.C. 1395w–153) is amended—

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

(B) in paragraph (3), by striking the period at the end and inserting a semicolon; and

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

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

“(5) have entered into and have in effect an agreement described in subsection (b) of such section 1860D–14B with the Secretary; and

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

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

“(b) EFFECTIVE DATE.—Paragraphs (1) through (3) of subsection (a) shall apply to covered part D drugs dispensed under this part on or after January 1, 2011, and before January 1, 2024, and paragraphs (4) through (6) of such subsection shall apply to covered part D drugs dispensed on or after January 1, 2024.”; and
(3) in subsection (c), by striking paragraph (2) and inserting the following:

“(2) the Secretary determines that in the period beginning on January 1, 2011, and ending on December 31, 2011 (with respect to paragraphs (1) through (3) of subsection (a)), or the period beginning on January 1, 2024, and ending December 31, 2024 (with respect to paragraphs (4) through (6) of such subsection), there were extenuating circumstances.”.

(h) 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 2024 an increase in the initial”;

(B) in subsection (e)(1)(C)—

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

and

(ii) by inserting “for a year preceding 2024 or the annual out-of-pocket threshold specified in subsection (b)(4)(B) for the year for 2024 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 pre-
ceding 2024 an initial”.

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

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

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

(B) in paragraph (2)—

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

(ii) in subparagraph (E)—

(I) by inserting ‘‘for a year preceding 2024,’’ after ‘‘subsection (c)’’; and


(A) by striking ‘‘the value of any discount’’ and inserting the following: ‘‘the value of—

‘‘(i) for years prior to 2024, 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 2024 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 2024” after “1860D–2(b)(3)”; and

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

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

SEC. 3. MONTHLY OUT-OF-POCKET COST SHARING MAXIMUM FOR ENROLLEES WHO INCUR A SIGNIFICANT PORTION OF COSTS TOWARDS ANNUAL OUT-OF-POCKET THRESHOLD.

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

(1) in paragraph (2)—

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

(B) by adding at the end the following new subparagraph:
“(E) MONTHLY OUT-OF-POCKET COST
SHARING MAXIMUM FOR ENROLLEES WHO
INCUR A SIGNIFICANT PORTION OF COSTS TO-
WARDS ANNUAL OUT-OF-POCKET THRESH-
OLD.—

“(i) ESTABLISHMENT OF PROCESS.—

“(I) IN GENERAL.—For plan
years beginning on or after January
1, 2024, the Secretary shall, through
notice and comment rulemaking, es-
tablish a process under which each
PDP sponsor offering a prescription
drug plan and each MA organization
offering an MA–PD plan shall each
plan year automatically enroll applica-
tible enrollees in the option to have
their monthly out-of-pocket cost-shar-
ing under the plan capped and paid in
monthly installments in accordance
with this subparagraph (referred to in
this subparagraph as the ‘monthly
out-of-pocket cost sharing maximum
option’).

“(II) OPT OUT.—The process es-
tablished under this clause shall per-
mit an applicable enrollee, prior to the beginning of the plan year or at any point during the plan year, to opt out of enrollment in the monthly out-of-pocket cost sharing maximum option and pay any out-of-pocket cost-sharing otherwise applicable for any covered part D drug in full at the time of the dispensing of such drug (or at the time of such opt out in the case of costs incurred during such enrollment that have not yet been billed to the enrollee).

“(ii) Definitions.—

“(I) Applicable enrollee.—
In this subparagraph, the term ‘applicable enrollee’ means any enrollee in a prescription drug plan or an MA–PD plan, including an enrollee who is a subsidy eligible individual (as defined in paragraph (3) of section 1860D–14(a)), who incurs or is likely to incur a significant percentage of costs for covered part D drugs.
“(II) Significant percentage.—For purposes of subclause (I), the Secretary shall, in the rulemaking under clause (i), define the term ‘significant percentage’ with respect to a percentage of the annual out-of-pocket threshold specified in paragraph (4)(B) but in no case shall the ‘significant percentage’ be less than 50 percent or more than 100 percent of the annual out-of-pocket threshold.

“(iii) Determination of monthly out-of-pocket cost sharing maximum.—For each month in a plan year in which an applicable enrollee is enrolled in the monthly out-of-pocket cost sharing maximum option, the PDP sponsor or MA organization shall determine a monthly out-of-pocket cost sharing maximum (as defined in clause (v)) for such enrollee.

“(iv) Beneficiary monthly payments.—With respect to an applicable enrollee who is enrolled in the monthly out-of-pocket cost sharing maximum option, for each month described in clause (iii),
the PDP sponsor or MA organization shall bill such enrollee an amount (not to exceed the monthly out-of-pocket cost sharing maximum) for the out-of-pocket costs of such enrollee in such month.

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

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

“(aa) the annual out-of-pocket threshold specified in paragraph (4)(B) minus the incurred costs of the enrollee as described in paragraph (4)(C); divided by

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

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

“(aa) the sum of any remaining out-of-pocket costs owed
by the enrollee from a previous month that have not yet been billed to the enrollee and any additional costs incurred by the enrollee; divided by

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

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

“(I) SECRETARIAL RESPONSIBILITIES.—The Secretary shall provide information to part D eligible individuals on the monthly out-of-pocket cost sharing maximum option through educational materials, including through the notices provided under section 1804(a).

“(II) PDP SPONSOR AND MA ORGANIZATION RESPONSIBILITIES.—
Each PDP sponsor offering a prescription drug plan or MA organization offering an MA–PD plan—
“(aa) shall not limit the application of the monthly out-of-pocket cost sharing maximum option to certain covered part D drugs;

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

“(cc) shall include information on such option in enrollee educational materials, including the availability of the opt out under clause (i)(II);

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

“(ee) shall provide that a pharmacy, after receiving a notification described in item (dd)
with respect to an enrollee, in-
forms the enrollee of such notifi-
cation;

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

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

“(III) Failure to pay amount
billed under monthly out-of-

pocket cost sharing maximum op-
tion.—If an applicable enrollee fails
to pay the amount billed for a month
as required under this subparagraph,
the applicable enrollee’s enrollment in
the monthly out-of-pocket cost sharing
maximum option shall be terminated
and the enrollee shall pay the cost-
sharing otherwise applicable for any
covered part D drugs subsequently
dispensed to the enrollee up to the an-
nual out-of-pocket threshold specified
in paragraph (4)(B).

“(IV) Clarification regarding past due amounts.—Nothing in
this subparagraph shall be construed
as prohibiting a PDP sponsor or an
MA organization from billing an en-
rollee for an amount owed under this
subparagraph.

“(V) Treatment of unsettled balances.—Any unsettled bal-
ances with respect to amounts owed
under this subparagraph shall be
treated as plan losses and the Sec-
retary shall not be liable for any such
balances outside of those assumed as
losses estimated in plan bids.”; and

(2) in paragraph (4)—

(A) in subparagraph (C), by striking “and
subject to subparagraph (F)” and inserting
“and subject to subparagraphs (F) and (G)”; and

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

“(G) Inclusion of costs paid under monthly out-of-pocket cost sharing maximum option.—In applying subparagraph (A), with respect to an applicable enrollee who is enrolled in the monthly out-of-pocket cost sharing maximum option described in clause (i)(I) of paragraph (2)(E), costs shall be treated as incurred if such costs are paid by a PDP sponsor or an MA organization under the process provided under such paragraph.”.

(b) Application to alternative prescription drug coverage.—Section 1860D–2(c) of the Social Security Act (42 U.S.C. 1395w–102(c)) is amended by adding at the end the following new paragraph:

“(4) Same monthly out-of-pocket cost sharing maximum.—For plan years beginning on or after January 1, 2024, the monthly out-of-pocket cost sharing maximum for applicable enrollees under the process provided under subsection (b)(2)(E) shall apply to such coverage.”.