

1 year preceding 2024,” after “paragraph
2 (4),”; and

3 (ii) in clause (ii)(III), by striking
4 “and each subsequent year” and inserting
5 “, 2021, 2022, and 2023”; and

6 (C) in subparagraph (D)—

7 (i) in clause (i)—

8 (I) in the matter preceding sub-
9 clause (I), by inserting “for a year
10 preceding 2024,” after “paragraph
11 (4),”; and

12 (II) in subclause (I)(bb), by
13 striking “a year after 2018” and in-
14 serting “each of years 2018 through
15 2023”; and

16 (ii) in clause (ii)(V), by striking
17 “2019 and each subsequent year” and in-
18 serting “each of years 2019 through
19 2023”;

20 (2) in paragraph (3)(A)—

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

1 (B) in clause (ii), by striking “for a subse-
2 quent year” and inserting “for each of years
3 2007 through 2023”;

4 (3) in paragraph (4)—

5 (A) in subparagraph (A)—

6 (i) in clause (i)—

7 (I) by redesignating subclauses
8 (I) and (II) as items (aa) and (bb),
9 respectively, and indenting appro-
10 priately;

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

15 “(I) for a year preceding 2024,
16 the greater of—”;

17 (III) by striking the period at the
18 end of item (bb), as redesignated by
19 subclause (I), and inserting “; and”;
20 and

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

23 “(II) for 2024 and each suc-
24 ceeding year, \$0.”; and

25 (ii) in clause (ii)—

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

3 (II) by adding at the end the fol-
4 lowing new sentence: “The Secretary
5 shall continue to calculate the dollar
6 amounts specified in clause (i)(I)(aa),
7 including with the adjustment under
8 this clause, after 2023 for purposes of
9 section 1860D–14(a)(1)(D)(iii).”;

10 (B) in subparagraph (B)—

11 (i) in clause (i)—

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

14 (II) in subclause (VI)—

15 (aa) by striking “for a sub-
16 sequent year” and inserting “for
17 2021, 2022, and 2023”; and

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

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

23 “(VII) for 2024, is equal to
24 \$3,100; or

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

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

9 (C) in subparagraph (C)(i), by striking
10 “and for amounts” and inserting “and for a
11 year preceding 2024 for amounts”; and

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

15 (b) REDUCTION IN BENEFICIARY COINSURANCE.—

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

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

23 (B) by striking “25 PERCENT COINSUR-
24 ANCE.—Subject to” and inserting “COINSUR-
25 ANCE.—

1 “(i) IN GENERAL.—Subject to”;

2 (C) in each of subclauses (I) and (II), as
3 redesignated by subparagraph (A), by striking
4 “25 percent” and inserting “the applicable per-
5 centage (as defined in clause (ii))”; and

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

8 “(ii) APPLICABLE PERCENTAGE DE-
9 FINED.—For purposes of clause (i), the
10 term ‘applicable percentage’ means—

11 “(I) for a year preceding 2024,
12 25 percent; and

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

15 (2) CONFORMING AMENDMENT.—Section
16 1860D–14(a)(2)(D) of the Social Security Act (42
17 U.S.C. 1395w–114(a)(2)(D)) is amended by striking
18 “25 percent” and inserting “the applicable percent-
19 age”.

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

23 (1) in paragraph (1)—

24 (A) by striking “equal to 80 percent” and
25 inserting “equal to—

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

3 (B) in subparagraph (A), as added by
4 paragraph (1), by striking the period at the end
5 and inserting “; and”; and

6 (C) by adding at the end the following new
7 subparagraph:

8 “(B) for 2024 and each subsequent year,
9 the sum of—

10 “(i) an amount equal to the applicable
11 percentage specified in paragraph (5)(A) of
12 such allowable reinsurance costs attrib-
13 utable to that portion of gross prescription
14 drug costs as specified in paragraph (3) in-
15 curred in the coverage year after such indi-
16 vidual has incurred costs that exceed the
17 annual out-of-pocket threshold specified in
18 section 1860D–2(b)(4)(B) with respect to
19 applicable drugs (as defined in section
20 1860D–14B(g)(2)); and

21 “(ii) an amount equal to the applica-
22 ble percentage specified in paragraph
23 (5)(B) of allowable reinsurance costs at-
24 tributable to that portion of gross prescrip-
25 tion drug costs as specified in paragraph

1 (3) incurred in the coverage year after
2 such individual has incurred costs that ex-
3 ceed the annual out-of-pocket threshold
4 specified in section 1860D–2(b)(4)(B) with
5 respect to covered part D drugs that are
6 not applicable drugs (as so defined).”; and

7 (2) by adding at the end the following new
8 paragraph:

9 “(5) APPLICABLE PERCENTAGE SPECIFIED.—
10 For purposes of paragraph (1)(B), the applicable
11 percentage specified in this paragraph is—

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

14 “(i) for 2024, 60 percent;

15 “(ii) for 2025, 40 percent; and

16 “(iii) for 2026 and each subsequent
17 year, 20 percent; and

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

20 “(i) for 2024, 80 percent;

21 “(ii) for 2025, 60 percent; and

22 “(iii) for 2026 and each subsequent
23 year, 40 percent.”.

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

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

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

6 “(a) ESTABLISHMENT.—The Secretary shall estab-
7 lish a manufacturer discount program (in this section re-
8 ferred to as the ‘program’). Under the program, the Sec-
9 retary shall enter into agreements described in subsection
10 (b) with manufacturers and provide for the performance
11 of the duties described in subsection (c). The Secretary
12 shall establish a model agreement for use under the pro-
13 gram by not later than January 1, 2023, in consultation
14 with manufacturers, and allow for comment on such model
15 agreement.

16 “(b) TERMS OF AGREEMENT.—

17 “(1) IN GENERAL.—

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

24 “(B) PROVISION OF DISCOUNTED PRICES
25 AT THE POINT-OF-SALE.—The discounted prices

1 described in subparagraph (A) shall be provided
2 to the applicable beneficiary at the pharmacy or
3 by the mail order service at the point-of-sale of
4 an applicable drug.

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

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

20 “(4) LENGTH OF AGREEMENT.—

21 “(A) IN GENERAL.—An agreement under
22 this section shall be effective for an initial pe-
23 riod of not less than 12 months and shall be
24 automatically renewed for a period of not less

1 than 1 year unless terminated under subpara-
2 graph (B).

3 “(B) TERMINATION.—

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

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

24 “(I) if the termination occurs be-
25 fore January 30 of a plan year, as of

1 the day after the end of the plan year;
2 and

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

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

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

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

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

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

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

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

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

18 “(i) the negotiated price of the appli-
19 cable drug; and

20 “(ii) the discounted price of the appli-
21 cable drug;

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

1 health benefit plans or programs that provide
2 coverage or financial assistance for the pur-
3 chase or provision of prescription drug coverage
4 on behalf of applicable beneficiaries as the Sec-
5 retary may specify; and

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

11 “(2) MONITORING COMPLIANCE.—

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

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

21 “(3) COLLECTION OF DATA FROM PRESCRIP-
22 TION DRUG PLANS AND MA–PD PLANS.—The Sec-
23 retary may collect appropriate data from prescrip-
24 tion drug plans and MA–PD plans in a timeframe

1 that allows for discounted prices to be provided for
2 applicable drugs under this section.

3 “(d) ADMINISTRATION.—

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

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

12 “(3) CONTRACT WITH THIRD PARTIES.—The
13 Secretary shall enter into a contract with 1 or more
14 third parties to administer the requirements estab-
15 lished by the Secretary in order to carry out this
16 section. At a minimum, the contract with a third
17 party under the preceding sentence shall require
18 that the third party—

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

23 “(B) receive, distribute, or facilitate the
24 distribution of funds of manufacturers to ap-
25 propriate individuals or entities in order to

1 meet the obligations of manufacturers under
2 agreements under this section;

3 “(C) provide adequate and timely informa-
4 tion to manufacturers, consistent with the
5 agreement with the manufacturer under this
6 section, as necessary for the manufacturer to
7 fulfill its obligations under this section; and

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

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

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

22 “(6) FUNDING.—For purposes of carrying out
23 this section, the Secretary shall provide for the
24 transfer, from the Federal Supplementary Medical
25 Insurance Trust Fund under section 1841 to the

1 Centers for Medicare & Medicaid Services Program
2 Management Account, of \$4,000,000 for each of fis-
3 cal years 2021 through 2024, to remain available
4 until expended.”.

5 “(e) ENFORCEMENT.—

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

9 “(2) CIVIL MONEY PENALTY.—

10 “(A) IN GENERAL.—The Secretary shall
11 impose a civil money penalty on a manufacturer
12 that fails to provide applicable beneficiaries dis-
13 counts for applicable drugs of the manufacturer
14 in accordance with such agreement for each
15 such failure in an amount the Secretary deter-
16 mines is commensurate with the sum of—

17 “(i) the amount that the manufac-
18 turer would have paid with respect to such
19 discounts under the agreement, which will
20 then be used to pay the discounts which
21 the manufacturer had failed to provide;
22 and

23 “(ii) 25 percent of such amount.

24 “(B) APPLICATION.—The provisions of
25 section 1128A (other than subsections (a) and

1 (b)) shall apply to a civil money penalty under
2 this paragraph in the same manner as such
3 provisions apply to a penalty or proceeding
4 under section 1128A(a).

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

12 “(g) DEFINITIONS.—In this section:

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

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

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

20 “(C) has incurred costs for covered part D
21 drugs in the year that are above the annual de-
22 ductible specified in section 1860D–2(b)(1) for
23 such year.

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

4 “(A) approved under a new drug applica-
5 tion under section 505(c) of the Federal Food,
6 Drug, and Cosmetic Act or, in the case of a bio-
7 logic product, licensed under section 351 of the
8 Public Health Service Act (including a product
9 licensed under subsection (k) of such section
10 351); and

11 “(B)(i) if the PDP sponsor of the prescrip-
12 tion drug plan or the MA organization offering
13 the MA–PD plan uses a formulary, which is on
14 the formulary of the prescription drug plan or
15 MA–PD plan that the applicable beneficiary is
16 enrolled in;

17 “(ii) if the PDP sponsor of the prescrip-
18 tion drug plan or the MA organization offering
19 the MA–PD plan does not use a formulary, for
20 which benefits are available under the prescrip-
21 tion drug plan or MA–PD plan that the appli-
22 cable beneficiary is enrolled in; or

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

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

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

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

8 “(4) DISCOUNTED PRICE.—

9 “(A) IN GENERAL.—Except as provided in
10 subparagraph (B), the term ‘discounted price’
11 means 90 percent of the negotiated price of the
12 applicable drug of a manufacturer.

13 “(B) PHASE-IN FOR CERTAIN DRUGS DIS-
14 PENSED FOR SUBSIDY ELIGIBLE INDIVID-
15 UALS.—

16 “(i) IN GENERAL.—In the case of an
17 applicable drug of a specified manufacturer
18 (as defined in clause (ii)) that is dispensed
19 for an applicable beneficiary who is a sub-
20 sidy eligible individual (as defined in sec-
21 tion 1860D–14(a)(3)), the term ‘dis-
22 counted price’ means the specified LIS
23 percent (as defined in clause (iii)) of the
24 negotiated price of the applicable drug of
25 the manufacturer.

1 “(ii) SPECIFIED MANUFACTURER.—In
2 this subparagraph, the term ‘specified
3 manufacturer’ means a manufacturer of an
4 applicable drug for which, in the calendar
5 year 2 years prior to the current plan year
6 (referred to in this clause as the ‘applicable
7 period’), the total reimbursement under
8 this title during the applicable period rep-
9 resented less than 1 percent of the total re-
10 imbursement under this title for all pre-
11 scription drugs during such period.

12 “(iii) SPECIFIED LIS PERCENT.—In
13 this subparagraph, the term ‘specified LIS
14 percent’ means—

15 “(I) for 2024, 98 percent;

16 “(II) for 2025, 97 percent;

17 “(III) for 2026, 96 percent;

18 “(IV) for 2027, 95 percent;

19 “(V) for 2028, 94 percent;

20 “(VI) for 2029, 93 percent;

21 “(VII) for 2030, 92 percent;

22 “(VIII) for 2031, 91 percent;

23 and

24 “(IX) for 2032 and each subse-

25 quent year, 90 percent.

1 “(C) CLARIFICATION.—Nothing in this
2 section shall be construed as affecting the re-
3 sponsibility of an applicable beneficiary for pay-
4 ment of a dispensing fee for an applicable drug.

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

15 “(6) NEGOTIATED PRICE.—The term ‘nego-
16 tiated price’ has the meaning given such term in sec-
17 tion 1860D–2(d)(1)(B), except that such negotiated
18 price shall not include any dispensing fee for the ap-
19 plicable 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 to applicable drugs dispensed on or after Jan-
11 uary 1, 2024, and, subject to paragraph (2), agree-
12 ments under this section shall be terminated as of
13 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 ities and duties) shall continue to apply after Janu-
18 ary 1, 2024, 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)—

1 (i) by striking “assumptions regarding
2 the reinsurance” and inserting “assump-
3 tions regarding—
4 “(I) the reinsurance”; and
5 (ii) by adding at the end the fol-
6 lowing:
7 “(II) for 2024 and each subse-
8 quent year, the manufacturer dis-
9 counts provided under section 1860D-
10 14B subtracted from the actuarial
11 value to produce such bid; and”; and
12 (B) in subsection (c)(1)(C)—
13 (i) by striking “an actuarial valuation
14 of the reinsurance” and inserting “an ac-
15 tuarial valuation of—
16 “(i) the reinsurance”;
17 (ii) in clause (i), as added by clause
18 (i) of this subparagraph, by adding “and”
19 at the end; and
20 (iii) by adding at the end the fol-
21 lowing:
22 “(ii) for 2024 and each subsequent
23 year, the manufacturer discounts provided
24 under section 1860D–14B;”.

1 (4) CLARIFICATION REGARDING EXCLUSION OF
2 MANUFACTURER DISCOUNTS FROM TROOP.—Section
3 1860D–2(b)(4) of the Social Security Act (42
4 U.S.C. 1395w–102(b)(4)) is amended—

5 (A) in subparagraph (C), by inserting “and
6 subject to subparagraph (F)” after “subpara-
7 graph (E)”; and

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

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

15 (e) DETERMINATION OF ALLOWABLE REINSURANCE
16 COSTS.—Section 1860D–15(b) of the Social Security Act
17 (42 U.S.C. 1395w–115(b)) is amended—

18 (1) in paragraph (2)—

19 (A) by striking “COSTS.—For purposes”
20 and inserting “COSTS.—

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

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

1 “(B) INCLUSION OF MANUFACTURER DIS-
2 COUNTS ON APPLICABLE DRUGS.—For purposes
3 of applying subparagraph (A), the term ‘allow-
4 able reinsurance costs’ shall include the portion
5 of the negotiated price (as defined in section
6 1860D–14B(g)(6)) of an applicable drug (as
7 defined in section 1860D–14B(g)(2)) that was
8 paid by a manufacturer under the manufacturer
9 discount program under section 1860D–14B.”;
10 and

11 (2) in paragraph (3)—

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

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

19 (f) UPDATING RISK ADJUSTMENT METHODOLOGIES
20 TO ACCOUNT FOR PART D MODERNIZATION REDE-
21 SIGN.—Section 1860D–15(c) of the Social Security Act
22 (42 U.S.C. 1395w–115(c)) is amended by adding at the
23 end the following new paragraph:

24 “(3) UPDATING RISK ADJUSTMENT METH-
25 ODOLOGIES TO ACCOUNT FOR PART D MODERNIZA-

1 TION REDESIGN.—The Secretary shall update the
2 risk adjustment methodologies used to adjust bid
3 amounts pursuant to this subsection as appropriate
4 to take into account changes in benefits under this
5 part pursuant to the amendments made by section
6 30521 of the Amendment in the Nature of a Sub-
7 stitute to Committee Print for Subtitle E Relating
8 to Drug Pricing.”.

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

12 (1) in subsection (a)—

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

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

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

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

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

24 “(6) have entered into and have in effect, under
25 terms and conditions specified by the Secretary, a

1 contract with a third party that the Secretary has
2 entered into a contract with under subsection (d)(3)
3 of such section 1860D–14B.”;

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

6 “(b) EFFECTIVE DATE.—Paragraphs (1) through (3)
7 of subsection (a) shall apply to covered part D drugs dis-
8 pensed under this part on or after January 1, 2011, and
9 before January 1, 2024, and paragraphs (4) through (6)
10 of such subsection shall apply to covered part D drugs
11 dispensed on or after January 1, 2024.”; and

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

14 “(2) the Secretary determines that in the period
15 beginning on January 1, 2011, and ending on De-
16 cember 31, 2011 (with respect to paragraphs (1)
17 through (3) of subsection (a)), or the period begin-
18 ning on January 1, 2024, and ending December 31,
19 2024 (with respect to paragraphs (4) through (6) of
20 such subsection), there were extenuating cir-
21 cumstances.”.

22 (h) CONFORMING AMENDMENTS.—

23 (1) Section 1860D–2 of the Social Security Act
24 (42 U.S.C. 1395w–102) is amended—

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

5 (B) in subsection (c)(1)(C)—

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

9 (ii) by inserting “for a year preceding
10 2024 or the annual out-of-pocket threshold
11 specified in subsection (b)(4)(B) for the
12 year for 2024 and each subsequent year”
13 after “subsection (b)(3) for the year” each
14 place it appears; and

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

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

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

24 (A) in paragraph (1)—

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

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

7 (iii) in subparagraph (E), by striking
8 “The elimination” and inserting “For a
9 year preceding 2024, the elimination”; and
10 (B) in paragraph (2)—

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

15 (ii) in subparagraph (E)—
16 (I) by inserting “for a year pre-
17 ceding 2024,” after “subsection (e)”;
18 and

19 (II) by striking “1860D–
20 2(b)(4)(A)(i)(I)” and inserting
21 “1860D–2(b)(4)(A)(i)(I)(aa)”.

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

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

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

6 “*(i)* for years prior to 2024, any dis-
7 count”;

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

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

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

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

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

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

22 (i) **EFFECTIVE DATE.**—The amendments made by
23 subsections (a) through (h) of this section shall apply to
24 plan year 2024 and subsequent plan years.

1 (j) MONTHLY OUT-OF-POCKET COST SHARING MAX-
2 IMUM FOR ENROLLEES WHO INCUR A SIGNIFICANT POR-
3 TION OF COSTS TOWARDS ANNUAL OUT-OF-POCKET
4 THRESHOLD.—

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

8 (A) in paragraph (2)—

9 (i) in subparagraph (A), by striking
10 “and (D)” and inserting “, (D), and (E)”;
11 and

12 (ii) by adding at the end the following
13 new subparagraph:

14 “(E) MONTHLY OUT-OF-POCKET COST
15 SHARING MAXIMUM FOR ENROLLEES WHO
16 INCUR A SIGNIFICANT PORTION OF COSTS TO-
17 WARDS ANNUAL OUT-OF-POCKET THRESH-
18 OLD.—

19 “(i) ESTABLISHMENT OF PROCESS.—

20 “(I) IN GENERAL.—For plan
21 years beginning on or after January
22 1, 2024, the Secretary shall, through
23 notice and comment rulemaking, es-
24 tablish a process under which each
25 PDP sponsor offering a prescription

1 drug plan and each MA organization
2 offering an MA-PD plan shall each
3 plan year automatically enroll applica-
4 ble enrollees in the option to have
5 their monthly out-of-pocket cost-shar-
6 ing under the plan capped and paid in
7 monthly installments in accordance
8 with this subparagraph (referred to in
9 this subparagraph as the ‘monthly
10 out-of-pocket cost sharing maximum
11 option’).

12 “(II) OPT OUT.—The process es-
13 tablished under this clause shall per-
14 mit an applicable enrollee, prior to the
15 beginning of the plan year or at any
16 point during the plan year, to opt out
17 of enrollment in the monthly out-of-
18 pocket cost sharing maximum option
19 and pay any out-of-pocket cost-shar-
20 ing otherwise applicable for any cov-
21 ered part D drug in full at the time
22 of the dispensing of such drug (or at
23 the time of such opt out in the case
24 of costs incurred during such enroll-

1 ment that have not yet been billed to
2 the enrollee).

3 “(ii) DEFINITIONS.—

4 “ (I) APPLICABLE ENROLLEE.—

5 In this subparagraph, the term ‘appli-
6 cable enrollee’ means any enrollee in a
7 prescription drug plan or an MA–PD
8 plan, including an enrollee who is a
9 subsidy eligible individual (as defined
10 in paragraph (3) of section 1860D–
11 14(a)), who incurs or is likely to incur
12 a significant percentage of costs for
13 covered part D drugs.

14 “ (II) SIGNIFICANT PERCENT-

15 AGE.—For purposes of subclause (I),
16 the Secretary shall, in the rulemaking
17 under clause (i), define the term ‘sig-
18 nificant percentage’ with respect to a
19 percentage of the annual out-of-pocket
20 threshold specified in paragraph
21 (4)(B) but in no case shall the ‘sig-
22 nificant percentage’ be less than 50
23 percent or more than 100 percent of
24 the annual out-of-pocket threshold.

1 “(iii) DETERMINATION OF MONTHLY
2 OUT-OF-POCKET COST SHARING MAX-
3 IMUM.—For each month in a plan year in
4 which an applicable enrollee is enrolled in
5 the monthly out-of-pocket cost sharing
6 maximum option, the PDP sponsor or MA
7 organization shall determine a monthly
8 out-of-pocket cost sharing maximum (as
9 defined in clause (v)) for such enrollee.

10 “(iv) BENEFICIARY MONTHLY PAY-
11 MENTS.—With respect to an applicable en-
12 rollee who is enrolled in the monthly out-
13 of-pocket cost sharing maximum option,
14 for each month described in clause (iii),
15 the PDP sponsor or MA organization shall
16 bill such enrollee an amount (not to exceed
17 the monthly out-of-pocket cost sharing
18 maximum) for the out-of-pocket costs of
19 such enrollee in such month.

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

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

4 “(aa) the annual out-of-
5 pocket threshold specified in
6 paragraph (4)(B) minus the in-
7 curred costs of the enrollee as de-
8 scribed in paragraph (4)(C); di-
9 vided by

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

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

14 “(aa) the sum of any re-
15 maining out-of-pocket costs owed
16 by the enrollee from a previous
17 month that have not yet been
18 billed to the enrollee and any ad-
19 ditional costs incurred by the en-
20 rollee; divided by

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

23 “(vi) ADDITIONAL REQUIREMENTS.—

24 The following requirements shall apply
25 with respect to the monthly out-of-pocket

1 cost sharing maximum option under this
2 subparagraph:

3 “(I) SECRETARIAL RESPONSIBIL-
4 ITIES.—The Secretary shall provide
5 information to part D eligible individ-
6 uals on the monthly out-of-pocket cost
7 sharing maximum option through edu-
8 cational materials, including through
9 the notices provided under section
10 1804(a).

11 “(II) PDP SPONSOR AND MA OR-
12 GANIZATION RESPONSIBILITIES.—
13 Each PDP sponsor offering a pre-
14 scription drug plan or MA organiza-
15 tion offering an MA–PD plan—

16 “(aa) shall not limit the ap-
17 plication of the monthly out-of-
18 pocket cost sharing maximum op-
19 tion to certain covered part D
20 drugs;

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

1 “(cc) shall include informa-
2 tion on such option in enrollee
3 educational materials, including
4 the availability of the opt out
5 under clause (i)(II);

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

13 “(ee) shall provide that a
14 pharmacy, after receiving a noti-
15 fication described in item (dd)
16 with respect to an enrollee, in-
17 forms the enrollee of such notifi-
18 cation;

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

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

8 “(III) FAILURE TO PAY AMOUNT
9 BILLED UNDER MONTHLY OUT-OF-
10 POCKET COST SHARING MAXIMUM OP-
11 TION.—If an applicable enrollee fails
12 to pay the amount billed for a month
13 as required under this subparagraph,
14 the applicable enrollee’s enrollment in
15 the monthly out-of-pocket cost sharing
16 maximum option shall be terminated
17 and the enrollee shall pay the cost-
18 sharing otherwise applicable for any
19 covered part D drugs subsequently
20 dispensed to the enrollee up to the an-
21 nual out-of-pocket threshold specified
22 in paragraph (4)(B).

23 “(IV) CLARIFICATION REGARD-
24 ING PAST DUE AMOUNTS.—Nothing in
25 this subparagraph shall be construed

1 as prohibiting a PDP sponsor or an
2 MA organization from billing an en-
3 rollee for an amount owed under this
4 subparagraph.

5 “(V) TREATMENT OF UNSET-
6 TLED BALANCES.—Any unsettled bal-
7 ances with respect to amounts owed
8 under this subparagraph shall be
9 treated as plan losses and the Sec-
10 retary shall not be liable for any such
11 balances outside of those assumed as
12 losses estimated in plan bids.”; and

13 (B) in paragraph (4)—

14 (i) in subparagraph (C), by striking
15 “and subject to subparagraph (F)” and in-
16 serting “and subject to subparagraphs (F)
17 and (G)”;

18 (ii) by adding at the end the following
19 new subparagraph:

20 “(G) INCLUSION OF COSTS PAID UNDER
21 MONTHLY OUT-OF-POCKET COST SHARING MAX-
22 IMUM OPTION.—In applying subparagraph (A),
23 with respect to an applicable enrollee who is en-
24 rolled in the monthly out-of-pocket cost sharing
25 maximum option described in clause (i)(I) of

1 paragraph (2)(E), costs shall be treated as in-
2 curred if such costs are paid by a PDP sponsor
3 or an MA organization under the process pro-
4 vided under such paragraph.”.

5 (2) APPLICATION TO ALTERNATIVE PRESCRIP-
6 TION DRUG COVERAGE.—Section 1860D–2(c) of the
7 Social Security Act (42 U.S.C. 1395w–102(c)) is
8 amended by adding at the end the following new
9 paragraph:

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

