

1 and each subsequent year, 15 percent)”;

2 and

3 (iii) in clause (ii), by inserting “(or,
4 for 2022 and each subsequent year, 15
5 percent)” after “25 percent”;

6 (B) in subparagraph (C)—

7 (i) in clause (i), in the matter pre-
8 ceding subclause (I), by inserting “for a
9 year preceding 2022,” after “paragraph
10 (4),”; and

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

14 (C) in subparagraph (D)—

15 (i) in clause (i)—

16 (I) in the matter preceding sub-
17 clause (I), by inserting “for a year
18 preceding 2022,” after “paragraph
19 (4),”; and

20 (II) in subclause (I)(bb), by
21 striking “a year after 2018” and in-
22 serting “each of years 2018 through
23 2021”; and

24 (ii) in clause (ii)(V), by striking
25 “2019 and each subsequent year” and in-

1 serting “each of years 2019 through
2 2021”;

3 (2) in paragraph (3)(A)—

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

7 (B) in clause (ii), by striking “for a subse-
8 quent year” and inserting “for each of years
9 2007 through 2021”;

10 (3) in paragraph (4)—

11 (A) in subparagraph (A)—

12 (i) in clause (i)—

13 (I) by redesignating subclauses
14 (I) and (II) as items (aa) and (bb),
15 respectively, and indenting appro-
16 priately;

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

21 “(I) for a year preceding 2022,
22 the greater of—”;

23 (III) by striking the period at the
24 end of item (bb), as redesignated by

1 subclause (I), and inserting “; and”;

2 and

3 (IV) by adding at the end the fol-
4 lowing:

5 “(II) for 2022 and each suc-
6 ceeding year, \$0.”; and

7 (ii) in clause (ii)—

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

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

17 (B) in subparagraph (B)—

18 (i) in clause (i)—

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

21 (II) in subclause (VI)—

22 (aa) by striking “for a sub-
23 sequent year” and inserting “for
24 2021”; and

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

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

6 “(VII) for 2022, is equal to
7 \$3,100; or

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

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

16 (C) in subparagraph (C)(i), by striking
17 “and for amounts” and inserting “and for a
18 year preceding 2022 for amounts”; and

19 (D) in subparagraph (E), by striking “In
20 applying” and inserting “For each of 2011
21 through 2021, in applying”.

22 (b) DECREASING REINSURANCE PAYMENT
23 AMOUNT.—Section 1860D–15(b)(1) of the Social Security
24 Act (42 U.S.C. 1395w–115(b)(1)) is amended—

1 (1) by striking “equal to 80 percent” and in-
2 sserting “equal to—

3 “(A) for a year preceding 2022, 80 per-
4 cent”;

5 (2) in subparagraph (A), as added by para-
6 graph (1), by striking the period at the end and in-
7 sserting “; and”; and

8 (3) by adding at the end the following new sub-
9 paragraph:

10 “(B) for 2022 and each subsequent year,
11 the sum of—

12 “(i) an amount equal to 20 percent of
13 the allowable reinsurance costs (as speci-
14 fied in paragraph (2)) attributable to that
15 portion of gross covered prescription drug
16 costs as specified in paragraph (3) in-
17 curred in the coverage year after such indi-
18 vidual has incurred costs that exceed the
19 annual out-of-pocket threshold specified in
20 section 1860D–2(b)(4)(B) with respect to
21 applicable drugs (as defined in section
22 1860D–14B(g)(2)); and

23 “(ii) an amount equal to 30 percent of
24 the allowable reinsurance costs (as speci-
25 fied in paragraph (2)) attributable to that

1 portion of gross covered prescription drug
2 costs as specified in paragraph (3) in-
3 curred in the coverage year after such indi-
4 vidual has incurred costs that exceed the
5 annual out-of-pocket threshold specified in
6 section 1860D–2(b)(4)(B) with respect to
7 covered part D drugs that are not applica-
8 ble drugs (as so defined).”.

9 (c) MANUFACTURER DISCOUNT PROGRAM.—

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

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

15 “(a) ESTABLISHMENT.—The Secretary shall estab-
16 lish a manufacturer discount program (in this section re-
17 ferred to as the ‘program’). Under the program, the Sec-
18 retary shall enter into agreements described in subsection
19 (b) with manufacturers and provide for the performance
20 of the duties described in subsection (c). The Secretary
21 shall establish a model agreement for use under the pro-
22 gram by not later than January 1, 2023, in consultation
23 with manufacturers, and allow for comment on such model
24 agreement.

25 “(b) TERMS OF AGREEMENT.—

1 “(1) IN GENERAL.—

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

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

14 “(2) PROVISION OF APPROPRIATE DATA.—Each
15 manufacturer with an agreement in effect under this
16 section shall collect and have available appropriate
17 data, as determined by the Secretary, to ensure that
18 it can demonstrate to the Secretary compliance with
19 the requirements under the program.

20 “(3) COMPLIANCE WITH REQUIREMENTS FOR
21 ADMINISTRATION OF PROGRAM.—Each manufac-
22 turer with an agreement in effect under this section
23 shall comply with requirements imposed by the Sec-
24 retary or a third party with a contract under sub-
25 section (d)(3), as applicable, for purposes of admin-

1 istering the program, including any determination
2 under subparagraph (A) of subsection (c)(1) or pro-
3 cedures established under such subsection (c)(1).

4 “(4) LENGTH OF AGREEMENT.—

5 “(A) IN GENERAL.—An agreement under
6 this section shall be effective for an initial pe-
7 riod of not less than 12 months and shall be
8 automatically renewed for a period of not less
9 than 1 year unless terminated under subpara-
10 graph (B).

11 “(B) TERMINATION.—

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

1 effective date to be repealed if the Sec-
2 retary determines appropriate.

3 “(ii) BY A MANUFACTURER.—A man-
4 ufacturer may terminate an agreement
5 under this section for any reason. Any
6 such termination shall be effective, with re-
7 spect to a plan year—

8 “(I) if the termination occurs be-
9 fore January 30 of a plan year, as of
10 the day after the end of the plan year;
11 and

12 “(II) if the termination occurs on
13 or after January 30 of a plan year, as
14 of the day after the end of the suc-
15 ceeding plan year.

16 “(iii) EFFECTIVENESS OF TERMI-
17 NATION.—Any termination under this sub-
18 paragraph shall not affect discounts for
19 applicable drugs of the manufacturer that
20 are due under the agreement before the ef-
21 fective date of its termination.

22 “(iv) NOTICE TO THIRD PARTY.—The
23 Secretary shall provide notice of such ter-
24 mination to a third party with a contract
25 under subsection (d)(3) within not less

1 than 30 days before the effective date of
2 such termination.

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

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

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

11 “(A) the determination of the amount of
12 the discounted price of an applicable drug of a
13 manufacturer;

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

19 “(C) the establishment of procedures to
20 ensure that, not later than the applicable num-
21 ber of calendar days after the dispensing of an
22 applicable drug by a pharmacy or mail order
23 service, the pharmacy or mail order service is
24 reimbursed for an amount equal to the dif-
25 ference between—

1 “(i) the negotiated price of the appli-
2 cable drug; and

3 “(ii) the discounted price of the appli-
4 cable drug;

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

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

19 “(2) MONITORING COMPLIANCE.—

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

23 “(B) NOTIFICATION.—If a third party
24 with a contract under subsection (d)(3) deter-
25 mines that the manufacturer is not in compli-

1 ance with such agreement, the third party shall
2 notify the Secretary of such noncompliance for
3 appropriate enforcement under subsection (e).

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

10 “(d) ADMINISTRATION.—

11 “(1) IN GENERAL.—Subject to paragraph (2),
12 the Secretary shall provide for the implementation of
13 this section, including the performance of the duties
14 described in subsection (e).

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

19 “(3) CONTRACT WITH THIRD PARTIES.—The
20 Secretary shall enter into a contract with 1 or more
21 third parties to administer the requirements estab-
22 lished by the Secretary in order to carry out this
23 section. At a minimum, the contract with a third
24 party under the preceding sentence shall require
25 that the third party—

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

5 “(B) receive, distribute, or facilitate the
6 distribution of funds of manufacturers to ap-
7 propriate individuals or entities in order to
8 meet the obligations of manufacturers under
9 agreements under this section;

10 “(C) provide adequate and timely informa-
11 tion to manufacturers, consistent with the
12 agreement with the manufacturer under this
13 section, as necessary for the manufacturer to
14 fulfill its obligations under this section; and

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

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

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

4 “(e) ENFORCEMENT.—

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

8 “(2) CIVIL MONEY PENALTY.—

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

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

22 “(ii) 25 percent of such amount.

23 “(B) APPLICATION.—The provisions of
24 section 1128A (other than subsections (a) and
25 (b)) shall apply to a civil money penalty under

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

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

10 “(g) DEFINITIONS.—In this section:

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

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

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

18 “(C) has incurred costs for covered part D
19 drugs in the year that are equal to or exceed
20 the annual deductible specified in section
21 1860D–2(b)(1) for such year.

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

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

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

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

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

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

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

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

5 “(4) DISCOUNTED PRICE.—

6 “(A) IN GENERAL.—The term ‘discounted
7 price’ means, with respect to an applicable drug
8 of a manufacturer furnished during a year to
9 an applicable beneficiary, 90 percent of the ne-
10 gotiated price of such drug.

11 “(B) CLARIFICATION.—Nothing in this
12 section shall be construed as affecting the re-
13 sponsibility of an applicable beneficiary for pay-
14 ment of a dispensing fee for an applicable drug.

15 “(C) SPECIAL CASE FOR CLAIMS SPANNING
16 DEDUCTIBLE.—In the case where the entire
17 amount of the negotiated price of an individual
18 claim for an applicable drug with respect to an
19 applicable beneficiary does not fall at or above
20 the annual deductible specified in section
21 1860D–2(b)(1) for the year, the manufacturer
22 of the applicable drug shall provide the dis-
23 counted price under this section on only the
24 portion of the negotiated price of the applicable

1 drug that falls at or above such annual deduct-
2 ible.

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

13 “(6) NEGOTIATED PRICE.—The term ‘nego-
14 tiated price’ has the meaning given such term in sec-
15 tion 1860D–2(d)(1)(B), except that such negotiated
16 price shall not include any dispensing fee for an ap-
17 plicable drug.

18 “(7) QUALIFIED RETIREE PRESCRIPTION DRUG
19 PLAN.—The term ‘qualified retiree prescription drug
20 plan’ has the meaning given such term in section
21 11860D–22(a)(2).”.

22 (2) SUNSET OF MEDICARE COVERAGE GAP DIS-
23 COUNT PROGRAM.—Section 1860D–14A of the So-
24 cial Security Act (42 U.S.C. 1395–114a) is amend-
25 ed—

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

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

6 “(h) SUNSET OF PROGRAM.—

7 “(1) IN GENERAL.—The program shall not
8 apply to applicable drugs dispensed on or after Jan-
9 uary 1, 2024, and, subject to paragraph (2), agree-
10 ments under this section shall be terminated as of
11 such date.

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

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

22 (A) in subsection (b)(2)(C)(iii)—

23 (i) by striking “assumptions regarding
24 the reinsurance” and inserting “assump-
25 tions regarding—

1 “(I) the reinsurance”; and

2 (ii) by adding at the end the fol-
3 lowing:

4 “(II) for 2024 and each subse-
5 quent year, the manufacturer dis-
6 counts provided under section 1860D-
7 14B subtracted from the actuarial
8 value to produce such bid; and”;

9 (B) in subsection (c)(1)(C)—

10 (i) by striking “an actuarial valuation
11 of the reinsurance” and inserting “an ac-
12 tuarial valuation of—

13 “(i) the reinsurance”;

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

17 (iii) by adding at the end the fol-
18 lowing:

19 “(ii) for 2024 and each subsequent
20 year, the manufacturer discounts provided
21 under section 1860D-14B;”.

22 (4) CLARIFICATION REGARDING EXCLUSION OF
23 MANUFACTURER DISCOUNTS FROM TROOP.—Section
24 1860D-2(b)(4) of the Social Security Act (42
25 U.S.C. 1395w-102(b)(4)) is amended—

1 (A) in subparagraph (C), by inserting “and
2 subject to subparagraph (F)” after “subpara-
3 graph (E)”; and

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

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

11 (d) DETERMINATION OF ALLOWABLE REINSURANCE
12 COSTS.—Section 1860D–15(b) of the Social Security Act
13 (42 U.S.C. 1395w–115(b)) is amended—

14 (1) in paragraph (2)—

15 (A) by striking “COSTS.—For purposes”
16 and inserting “COSTS.—

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

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

21 “(B) INCLUSION OF MANUFACTURER DIS-
22 COUNTS ON APPLICABLE DRUGS.—For purposes
23 of applying subparagraph (A), the term ‘allow-
24 able reinsurance costs’ shall include the portion
25 of the negotiated price (as defined in section

1 1860D–14B(g)(6)) of an applicable drug (as
2 defined in section 1860D–14(g)(2)) that was
3 paid by a manufacturer under the manufacturer
4 discount program under section 1860D–14B.”;
5 and

6 (2) in paragraph (3)—

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

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

14 (e) UPDATING RISK ADJUSTMENT METHODOLOGIES
15 TO ACCOUNT FOR PART D MODERNIZATION REDESIGN.—

16 Section 1860D–15(c) of the Social Security Act (42
17 U.S.C. 1395w–115(e)) is amended by adding at the end
18 the following new paragraph:

19 “(3) UPDATING RISK ADJUSTMENT METH-
20 ODOLOGIES TO ACCOUNT FOR PART D MODERNIZA-
21 TION REDESIGN.—The Secretary shall update the
22 risk adjustment model used to adjust bid amounts
23 pursuant to this subsection as appropriate to take
24 into account changes in benefits under this part pur-

1 suant to the amendments made by section 121 of
2 the Lower Costs, More Cures Act of 2021.”.

3 (f) CONDITIONS FOR COVERAGE OF DRUGS UNDER
4 THIS PART.—Section 1860D–43 of the Social Security
5 Act (42 U.S.C. 1395w–153) is amended—

6 (1) in subsection (a)—

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

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

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

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

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

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

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

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

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

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

17 (g) CONFORMING AMENDMENTS.—

18 (1) Section 1860D–2 of the Social Security Act
19 (42 U.S.C. 1395w–102) is amended—

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

24 (B) in subsection (c)(1)(C)—

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

4 (ii) by inserting “for a year preceding
5 2024 or the annual out-of-pocket threshold
6 specified in subsection (b)(4)(B) for the
7 year for 2024 and each subsequent year”
8 after “subsection (b)(3) for the year” each
9 place it appears; and

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

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

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

19 (A) in paragraph (1)—

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

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

1 (iii) in subparagraph (E), by striking
2 “The elimination” and inserting “For a
3 year preceding 2024, the elimination”; and
4 (B) in paragraph (2)—

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

9 (ii) in subparagraph (E)—
10 (I) by inserting “for a year pre-
11 ceding 2024,” after “subsection (e)”;
12 and

13 (II) by striking “1860D-
14 2(b)(4)(A)(i)(I)” and inserting
15 “1860D-2(b)(4)(A)(i)(I)(aa)”.

16 (4) Section 1860D-21(d)(7) of the Social Secu-
17 rity Act (42 U.S.C. 1395w-131(d)(7)) is amended
18 by striking “section 1860D-2(b)(4)(B)(i)” and in-
19 serting “section 1860D-2(b)(4)(C)(i)”.

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

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

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

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

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

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

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

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

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

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

1 **Subtitle C—Other Medicare Part D**
2 **Provisions**

3 **SEC. 131. ALLOWING THE OFFERING OF ADDITIONAL PRE-**
4 **SCRIPTION DRUG PLANS UNDER MEDICARE**
5 **PART D.**

6 (a) RESCINDING AND ISSUANCE OF NEW GUID-
7 ANCE.—Not later than one year after the date of the en-
8 actment of this Act, the Secretary of Health and Human
9 Services (in this section referred to as the “Secretary”)
10 shall—

11 (1) rescind sections of any sub-regulatory guid-
12 ance that limit the number of prescription drug
13 plans in each PDP region that may be offered by a
14 PDP sponsor under part D of title XVIII of the So-
15 cial Security Act (42 U.S.C. 1395w–101 et seq.);
16 and

17 (2) issue new guidance specifying that a PDP
18 sponsor may offer up to 4 (or a greater number if
19 determined appropriate by the Secretary) prescrip-
20 tion drug plans in each PDP region, except in cases
21 where the PDP sponsor may offer up to 2 additional
22 plans in a PDP region pursuant to section 1860D–
23 11(d)(4) of the Social Security Act (42 U.S.C.
24 1395w–111(d)(4)), as added by subsection (b).

1 (b) OFFERING OF ADDITIONAL PLANS.—Section
2 1860D–11(d) of the Social Security Act (42 U.S.C.
3 1395w–111(d)) is amended by adding at the end the fol-
4 lowing new paragraph:

5 “(4) OFFERING OF ADDITIONAL PLANS.—

6 “(A) IN GENERAL.—For plan year 2022
7 and each subsequent plan year, a PDP sponsor
8 may offer up to 2 additional prescription drug
9 plans in a PDP region (in addition to any limit
10 established by the Secretary under this part)
11 provided that the PDP sponsor complies with
12 subparagraph (B) with respect to at least one
13 such prescription drug plan.

14 “(B) REQUIREMENTS.—In order to be eli-
15 gible to offer up to 2 additional plans in a PDP
16 region pursuant to subparagraph (A), a PDP
17 sponsor must ensure that, with respect to at
18 least one such prescription drug plan, the spon-
19 sor or any entity that provides pharmacy bene-
20 fits management services under a contract with
21 any such sponsor or plan does not receive direct
22 or indirect remuneration, as defined in section
23 423.308 of title 42, Code of Federal Regula-
24 tions (or any successor regulation), unless at
25 least 25 percent of the aggregate reductions in

1 price or other remuneration received by the
2 PDP sponsor or entity from drug manufactur-
3 ers with respect to the plan and plan year—

4 “(i) are reflected at the point-of-sale
5 to the enrollee; or

6 “(ii) are used to reduce total bene-
7 ficiary cost-sharing estimated by the PDP
8 sponsor for prescription drug coverage
9 under the plan in the annual bid submitted
10 by the PDP sponsor under section 1860D-
11 11(b).

12 “(C) DEFINITION OF REDUCTIONS IN
13 PRICE.—For purposes of subparagraph (B), the
14 term ‘reductions in price’ refers only to collect-
15 ible amounts, as determined by the Secretary,
16 which excludes amounts which after adjudica-
17 tion and reconciliation with pharmacies and
18 manufacturers are duplicate in nature, contrary
19 to other contractual clauses, or otherwise ineli-
20 gible (such as due to beneficiary disenrollment
21 or coordination of benefits).”.

22 (c) RULE OF CONSTRUCTION.—Nothing in the provi-
23 sions of, or amendments made by, this section shall be
24 construed as limiting the ability of the Secretary to in-
25 crease any limit otherwise applicable on the number of

1 prescription drug plans that a PDP sponsor may offer,
2 at the discretion of the PDP sponsor, in a PDP region
3 under part D of title XVIII of the Social Security Act (42
4 U.S.C. 1395w–101 et seq.).

5 **SEC. 132. ALLOWING CERTAIN ENROLLEES OF PRESCRIP-**
6 **TION DRUG PLANS AND MA-PD PLANS UNDER**
7 **MEDICARE PROGRAM TO SPREAD OUT COST-**
8 **SHARING UNDER CERTAIN CIRCUMSTANCES.**

9 (a) STANDARD PRESCRIPTION DRUG COVERAGE.—
10 Section 1860D–2(b)(2) of the Social Security Act (42
11 U.S.C. 1395w–102(b)(2)), as amended by section 121, is
12 further amended—

13 (1) in subparagraph (A), by striking “Subject
14 to subparagraphs (C) and (D)” and inserting “Sub-
15 ject to subparagraphs (C), (D), and (E)”; and

16 (2) by adding at the end the following new sub-
17 paragraph:

18 “(E) ENROLLEE OPTION REGARDING
19 SPREADING COST-SHARING.—

20 “(i) IN GENERAL.—The Secretary
21 shall establish by regulation a process
22 under which, with respect to plan year
23 2022 and subsequent plan years, a pre-
24 scription drug plan or an MA–PD plan
25 shall, in the case of a part D eligible indi-

1 vidual enrolled with such plan for such
2 plan year with respect to whom the plan
3 projects that the dispensing of a covered
4 part D drug to such individual will result
5 in the individual incurring costs within a
6 30-day period that are equal to a signifi-
7 cant percentage (as specified by the Sec-
8 retary pursuant to such regulation) of the
9 annual out-of-pocket threshold specified in
10 paragraph (4)(B) for such plan year, pro-
11 vide such individual with the option to
12 make the coinsurance payment required
13 under subparagraph (A) for such costs in
14 the form of equal monthly installments
15 over the remainder of such plan year.

16 “(ii) SIGNIFICANT PERCENTAGE LIM-
17 TATIONS.—In specifying a significant per-
18 centage pursuant to the regulation estab-
19 lished by the Secretary under clause (i),
20 the Secretary may not specify a percentage
21 that is less than 30 percent or greater
22 than 100 percent.”.

23 (b) ALTERNATIVE PRESCRIPTION DRUG COV-
24 ERAGE.—Section 1860D–2(c) of the Social Security Act

1 (42 U.S.C. 1395w–102(c)) is amended by adding at the
2 end the following new paragraph:

3 “(4) SAME ENROLLEE OPTION REGARDING
4 SPREADING COST-SHARING.—For plan year 2022
5 and subsequent plan years, the coverage provides the
6 enrollee option regarding spreading cost-sharing de-
7 scribed in and required under subsection
8 (b)(2)(E).”.

9 **SEC. 133. ESTABLISHING A MONTHLY CAP ON BENEFICIARY**
10 **INCURRED COSTS FOR INSULIN PRODUCTS**
11 **AND SUPPLIES UNDER A PRESCRIPTION**
12 **DRUG PLAN OR MA–PD PLAN.**

13 (a) IN GENERAL.—Section 1860D–2 of the Social
14 Security Act (42 U.S.C. 1395w–102), as amended by sec-
15 tions 121 and 133, is further amended—

16 (1) in subsection (b)(2)—

17 (A) in subparagraph (A), by striking “and
18 (E)” and inserting “(E), and (F)”;

19 (B) in subparagraph (B), by striking “and
20 (D)” and inserting “(D), and (F)”;

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

23 “(F) CAP ON INCURRED COSTS FOR INSU-
24 LIN PRODUCTS AND SUPPLIES.—

1 “(i) IN GENERAL.—The coverage pro-
2 vides benefits, for costs above the annual
3 deductible specified in paragraph (1) and
4 up to the annual out-of-pocket threshold
5 described in paragraph (4)(B) and with re-
6 spect to a month (beginning with January
7 of 2022), with cost sharing that is equal to
8 \$0 for a specified covered part D drug (as
9 defined in clause (iii)) furnished to an indi-
10 vidual who has incurred costs during such
11 month with respect to specified covered
12 part D drugs equal to—

13 “(I) for months occurring in
14 2022, \$50; or

15 “(II) for months occurring in a
16 subsequent year, the amount applica-
17 ble under this clause for months oc-
18 curring in the year preceding such
19 subsequent year, increased by the an-
20 nual percentage increase specified in
21 paragraph (6) for such subsequent
22 year and rounded to the nearest dol-
23 lar.

24 “(ii) APPLICATION.—The provisions
25 of clauses (i) through (iii) of paragraph

1 (4)(C) shall apply with respect to the de-
2 termination of the incurred costs for speci-
3 fied covered part D drugs for purposes of
4 clause (i) in the same manner as such pro-
5 visions apply with respect to the deter-
6 mination of incurred costs for covered part
7 D drugs for purposes of paragraph (4)(A).

8 “(iii) SPECIFIED COVERED PART D
9 DRUG.—For purposes of this subpara-
10 graph, the term ‘specified covered part D
11 drug’ means a covered part D drug that
12 is—

13 “(I) insulin; or

14 “(II) a medical supply associated
15 with the injection of insulin (as de-
16 fined in regulations of the Secretary
17 promulgated pursuant to subsection
18 (e)(1)(B)).”; and

19 (2) in subsection (c), by adding at the end the
20 following new paragraph:

21 “(5) SAME PROTECTION WITH RESPECT TO EX-
22 PENDITURES FOR INSULIN AND CERTAIN MEDICAL
23 SUPPLIES.—The coverage provides the coverage re-
24 quired under subsection (b)(2)(F).”.

25 (b) CONFORMING AMENDMENTS.—

1 (1) IN GENERAL.—Section 1860D–14(a)(1)(D)
2 of the Social Security Act (42 U.S.C. 1395w–
3 114(a)(1)(D)), as amended by section 121, is fur-
4 ther amended—

5 (A) in clause (ii), by striking “section
6 1860D–2(b)(2)” and inserting “section 1860D–
7 2(b)(2)(A)”; and

8 (B) in clause (iii), by striking “section
9 1860D–2(b)(2)” and inserting “section 1860D–
10 2(b)(2)(A)”.

11 (2) EFFECTIVE DATE.—The amendments made
12 by paragraph (1) shall apply with respect to plan
13 year 2022 and each subsequent plan year.

14 **SEC. 134. GROWTH RATE OF MEDICARE PART D OUT-OF-**
15 **POCKET COST THRESHOLD.**

16 (a) PROVIDING MEDICARE PART D BENEFICIARIES
17 WITH CERTAIN 2020 OFFSET PAYMENTS.—Section
18 1860D–2(b)(4) of the Social Security Act (42 U.S.C.
19 1395w–102(b)(4)) is amended by adding at the end the
20 following new subparagraph:

21 “(F) 2020 OFFSET PAYMENTS.—

22 “(i) IN GENERAL.—Subject to clause
23 (iv), the Secretary shall provide for pay-
24 ment from the Medicare Prescription Drug
25 Account as follows:

1 “(I) In the case of a specified in-
2 dividual (as defined in clause (ii)(I))
3 who as of the last day of a calendar
4 quarter in 2020 has incurred costs for
5 covered part D drugs so that the indi-
6 vidual has exceeded the annual out-of-
7 pocket threshold applied under sub-
8 paragraph (B)(i)(V) for 2020, pay-
9 ment to the individual by not later
10 than 15th day of the third month fol-
11 lowing the end of such quarter of the
12 amount by which such threshold so
13 applied exceeded the target threshold
14 for 2020.

15 “(II) In the case of a specified
16 individual who is not described in sub-
17 clause (I) and who as of the last day
18 of 2020 has incurred costs for covered
19 part D drugs so that the individual
20 has exceeded the target threshold for
21 2020, payment to the individual by
22 not later than December 31, 2021, of
23 the amount by which such incurred
24 costs exceeded the target threshold for
25 2020.

1 “(ii) DEFINITIONS.—For purposes of
2 this subparagraph:

3 “(I) SPECIFIED INDIVIDUAL.—
4 The term ‘specified individual’ means
5 an individual who—

6 “(aa) is enrolled in a pre-
7 scription drug plan or an MA-
8 PD plan;

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

12 “(cc) is not entitled to an in-
13 come-related subsidy under sec-
14 tion 1860D–14(a).

15 “(II) TARGET THRESHOLD FOR
16 2020.—The term ‘target threshold for
17 2020’ means the annual out-of-pocket
18 threshold that would have been ap-
19 plied under subparagraph (B)(i) for
20 2020 if such threshold had been de-
21 termined in accordance with subclause
22 (IV) of such subparagraph instead of
23 subclause (V) of such subparagraph.

24 “(iii) NOTIFICATION.—In the case of
25 any specified individual who during 2020

1 has incurred costs for covered part D
2 drugs so that the individual has exceeded
3 the target threshold for 2020, the Sec-
4 retary shall, not later than September 30,
5 2021, provide to such individual a notifica-
6 tion informing such individual of such indi-
7 vidual’s right to a payment described in
8 clause (i) and the estimated timing of such
9 payment.

10 “(iv) CLARIFICATION.—The Secretary
11 shall provide only 1 payment under this
12 subparagraph with respect to any indi-
13 vidual.

14 “(v) IMPLEMENTATION.—The Sec-
15 retary may implement this subparagraph
16 by program instruction or otherwise.”.

17 (b) REDUCED GROWTH RATE FOR 2021 OF MEDI-
18 CARE PART D OUT-OF-POCKET COST THRESHOLD.—Sec-
19 tion 1860D–2(b)(4)(B)(i) of the Social Security Act (42
20 U.S.C. 1395w–102(b)(4)(B)(i)) is amended—

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

23 (2) by redesignating subclause (VI) as sub-
24 clause (VIII); and

1 (3) by inserting after subclause (V) the fol-
2 lowing new subclauses:

3 “(VI) for 2021, is equal to the
4 amount that would have been applied
5 under this subparagraph for 2020 if
6 such amount had been determined in
7 accordance with subclause (IV) in-
8 stead of subclause (V), increased by
9 the lesser of—

10 “(aa) the annual percentage
11 increase described in paragraph
12 (7) for 2021, plus 2 percentage
13 points; or

14 “(bb) the annual percentage
15 increase described in paragraph
16 (6) for 2021;

17 “(VII) for 2022, is equal to the
18 amount that would have been applied
19 under this subparagraph for 2022 if
20 the amendments made by section
21 1101(d)(1) of the Health Care and
22 Education Reconciliation Act of 2010
23 and by section 134 of subtitle B of
24 title I of the Act titled ‘An Act to pro-
25 vide for reconciliation pursu25 ant to

1 title II of S. Con. Res. 14' had not
2 been enacted; or''.

