

**AMENDMENT TO THE AMENDMENT IN THE NA-  
TURE OF A SUBSTITUTE TO COMMITTEE  
PRINT FOR SUBTITLE E RELATING TO DRUG  
PRICING**

**OFFERED BY M**     .

Add at the end of part 3 the following new section:

1 **SEC. 30523. MEDICARE PART D BENEFIT REDESIGN.**

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

5 (1) in paragraph (2)—

6 (A) in subparagraph (A)—

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

14 (ii) in clause (i), by inserting after  
15 “25 percent” the following: “(or, for 2022  
16 and each subsequent year, 15 percent)”;  
17 and

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

4 (B) in subparagraph (C)—

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

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

12 (C) in subparagraph (D)—

13 (i) in clause (i)—

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

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

22 (ii) in clause (ii)(V), by striking  
23 “2019 and each subsequent year” and in-  
24 serting “each of years 2019 through  
25 2021”;

1 (2) in paragraph (3)(A)—

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

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

8 (3) in paragraph (4)—

9 (A) in subparagraph (A)—

10 (i) in clause (i)—

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

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

19 “(I) for a year preceding 2022,  
20 the greater of—”.

21 (III) by striking the period at the  
22 end of item (bb), as redesignated by  
23 subclause (I), and inserting “; and”;  
24 and

1 (IV) by adding at the end the fol-  
2 lowing:

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

5 (ii) in clause (ii)—

6 (I) by striking “clause (i)(I)” and  
7 inserting “clause (i)(I)(aa)”; and

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

15 (B) in subparagraph (B)—

16 (i) in clause (i)—

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

19 (II) in subclause (VI)—

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

23 (bb) by striking the period  
24 at the end and inserting a semi-  
25 colon; and

1 (III) by adding at the end the  
2 following new subclauses:

3 “(VII) for 2022, is equal to  
4 \$3,100; or

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

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

13 (C) in subparagraph (C)(i), by striking  
14 “and for amounts” and inserting “and for a  
15 year preceding 2022 for amounts”; and

16 (D) in subparagraph (E), by striking “In  
17 applying” and inserting “For each of 2011  
18 through 2021, in applying”.

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

22 (1) by striking “equal to 80 percent” and in-  
23 serting “equal to—

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

1           (2) in subparagraph (A), as added by para-  
2           graph (1), by striking the period at the end and in-  
3           serting “; and”; and

4           (3) by adding at the end the following new sub-  
5           paragraph:

6                   “(B) for 2022 and each subsequent year,  
7           the sum of—

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

19                           “(ii) an amount equal to 30 percent of  
20                           the allowable reinsurance costs (as speci-  
21                           fied in paragraph (2)) attributable to that  
22                           portion of gross covered prescription drug  
23                           costs as specified in paragraph (3) in-  
24                           curred in the coverage year after such indi-  
25                           vidual has incurred costs that exceed the

1           annual out-of-pocket threshold specified in  
2           section 1860D–2(b)(4)(B) with respect to  
3           covered part D drugs that are not applica-  
4           ble drugs (as so defined).”.

5           (c) MANUFACTURER DISCOUNT PROGRAM.—

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

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

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

21          “(b) TERMS OF AGREEMENT.—

22                  “(1) IN GENERAL.—

23                          “(A) AGREEMENT.—An agreement under  
24                          this section shall require the manufacturer to  
25                          provide applicable beneficiaries access to dis-

1           counted prices for applicable drugs of the man-  
2           ufacturer that are dispensed on or after Janu-  
3           ary 1, 2024.

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

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

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

25          “(4) LENGTH OF AGREEMENT.—



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

7           “(B) TERMINATION.—

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

23           “(ii) BY A MANUFACTURER.—A man-  
24 ufacturer may terminate an agreement  
25 under this section for any reason. Any

1 such termination shall be effective, with re-  
2 spect to a plan year—

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

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

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

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

23 “(5) EFFECTIVE DATE OF AGREEMENT.—An  
24 agreement under this section shall take effect on a

1 date determined appropriate by the Secretary, which  
2 may be at the start of a calendar quarter.

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

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

7 “(A) the determination of the amount of  
8 the discounted price of an applicable drug of a  
9 manufacturer;

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

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

22 “(i) the negotiated price of the appli-  
23 cable drug; and

24 “(ii) the discounted price of the appli-  
25 cable drug;

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

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

15           “(2) MONITORING COMPLIANCE.—

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

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

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

7           “(d) ADMINISTRATION.—

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

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

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

23                  “(A) receive and transmit information be-  
24                  tween the Secretary, manufacturers, and other

1 individuals or entities the Secretary determines  
2 appropriate;

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

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

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

18 “(4) PERFORMANCE REQUIREMENTS.—The  
19 Secretary shall establish performance requirements  
20 for a third party with a contract under paragraph  
21 (3) and safeguards to protect the independence and  
22 integrity of the activities carried out by the third  
23 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”; 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 “  
2 and subject to subparagraph (F)” after “sub-  
3 paragraph (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”.

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 **SEC. 30524. ESTABLISHING A MONTHLY CAP ON BENE-**  
2 **FICIARY INCURRED COSTS FOR INSULIN**  
3 **PRODUCTS AND SUPPLIES UNDER A PRE-**  
4 **SCRIPTION DRUG PLAN OR MAPD PLAN.**

5 (a) IN GENERAL.—Section 1860D–2 of the Social  
6 Security Act (42 U.S.C. 1395w–102), as amended by sec-  
7 tion 30523, is further amended—

8 (1) in subsection (b)(2)—

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

11 (B) in subparagraph (B), by striking “and  
12 (D)” and inserting “(D), and (F)”;

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

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

17 “(i) IN GENERAL.—The coverage pro-  
18 vides benefits, for costs above the annual  
19 deductible specified in paragraph (1) and  
20 up to the annual out-of-pocket threshold  
21 described in paragraph (4)(B) and with re-  
22 spect to a month (beginning with January  
23 of 2022), with cost sharing that is equal to  
24 \$0 for a specified covered part D drug (as  
25 defined in clause (iii)) furnished to an indi-  
26 vidual who has incurred costs during such

1 month with respect to specified covered  
2 part D drugs equal to—

3 “(I) for months occurring in  
4 2022, \$50; or

5 “(II) for months occurring in a  
6 subsequent year, the amount applica-  
7 ble under this clause for months oc-  
8 ccurring in the year preceding such  
9 subsequent year, increased by the an-  
10 nual percentage increase specified in  
11 paragraph (6) for such subsequent  
12 year and rounded to the nearest dol-  
13 lar.

14 “(ii) APPLICATION.—The provisions  
15 of clauses (i) through (iii) of paragraph  
16 (4)(C) shall apply with respect to the de-  
17 termination of the incurred costs for speci-  
18 fied covered part D drugs for purposes of  
19 clause (i) in the same manner as such pro-  
20 visions apply with respect to the deter-  
21 mination of incurred costs for covered part  
22 D drugs for purposes of paragraph (4)(A).

23 “(iii) SPECIFIED COVERED PART D  
24 DRUG.—For purposes of this subpara-  
25 graph, the term ‘specified covered part D

1 drug’ means a covered part D drug that  
2 is—

3 “(I) insulin; or

4 “(II) a medical supply associated  
5 with the injection of insulin (as de-  
6 fined in regulations of the Secretary  
7 promulgated pursuant to subsection  
8 (e)(1)(B)).”; and

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

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

15 (b) CONFORMING AMENDMENTS.—

16 (1) IN GENERAL.—Section 1860D–14(a)(1)(D)  
17 of the Social Security Act (42 U.S.C. 1395w–  
18 114(a)(1)(D)), as amended by section 121, is fur-  
19 ther amended—

20 (A) in clause (ii), by striking “section  
21 1860D–2(b)(2)” and inserting “section 1860D–  
22 2(b)(2)(A)”; and

23 (B) in clause (iii), by striking “section  
24 1860D–2(b)(2)” and inserting “section 1860D–  
25 2(b)(2)(A)”.

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

