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(Original Signature of Member)

119TH CONGRESS
1ST SESSION

H. R. _____

To expand the drug price negotiation program under title XI of the Social Security Act and repeal certain changes to the program made by Public Law 119–21, to apply prescription drug inflation rebates under the Medicare program to drugs furnished in the commercial market, and to establish out-of-pocket limits on expenditures for prescription drugs under private health insurance.

IN THE HOUSE OF REPRESENTATIVES

Mr. PALLONE (for himself, Mr. NEAL, and Mr. SCOTT of Virginia) introduced the following bill; which was referred to the Committee on

A BILL

To expand the drug price negotiation program under title XI of the Social Security Act and repeal certain changes to the program made by Public Law 119–21, to apply prescription drug inflation rebates under the Medicare program to drugs furnished in the commercial market, and to establish out-of-pocket limits on expenditures for prescription drugs under private health insurance.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Lowering Drug Costs
3 for American Families Act”.

4 **TITLE I—DRUG PRICE**
5 **NEGOTIATION PROGRAM**

6 **SEC. 101. EXPANDING THE DRUG PRICE NEGOTIATION PRO-**
7 **GRAM.**

8 (a) INCREASING THE NUMBER OF DRUGS SUBJECT
9 TO NEGOTIATION.—Section 1192(a)(4) of the Social Se-
10 curity Act (42 U.S.C. 1320f–1(a)(4)) is amended by strik-
11 ing “20” each place it appears and inserting “50” in each
12 such place.

13 (b) EXPANSION OF DEFINITION OF MAXIMUM FAIR
14 PRICE ELIGIBLE INDIVIDUAL.—Section 1191(c)(2) of the
15 Social Security Act (42 U.S.C. 1320f(c)(2)) is amended—

16 (1) in subparagraph (A), by inserting “, or a
17 participant, beneficiary, or enrollee who is enrolled
18 under a group health plan or health insurance cov-
19 erage offered in the group or individual market (as
20 such terms are defined in section 2791 of the Public
21 Health Service Act) with respect to which there is in
22 effect an agreement with the Secretary under section
23 1197 with respect to such selected drug as so fur-
24 nished or dispensed” after “such selected drug”; and

25 (2) in subparagraph (B), by inserting “, or a
26 participant, beneficiary, or enrollee who is enrolled

1 under a group health plan or health insurance cov-
2 erage offered in the group or individual market (as
3 such terms are defined in section 2791 of the Public
4 Health Service Act) with respect to which there is in
5 effect an agreement with the Secretary under section
6 1197 with respect to such selected drug as so fur-
7 nished or administered” after “such selected drug”.

8 (c) APPLICATION OF ADMINISTRATIVE PROCEDURES
9 TO NEW MAXIMUM FAIR PRICE ELIGIBLE INDIVID-
10 UALS.—Section 1196(a)(3) of the Social Security Act (42
11 U.S.C. 1320f–5(a)(3)) is amended—

12 (1) in subparagraph (A), by striking “and” at
13 the end;

14 (2) in subparagraph (B), by striking the period
15 and inserting “; and”; and

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

18 “(C) maximum fair price eligible individ-
19 uals not described in subparagraph (A) or
20 (B).”.

21 (d) HEALTH INSURER AGREEMENTS.—Part E of
22 title XI of the Social Security Act (42 U.S.C. 1320f et
23 seq.) is amended—

24 (1) by redesignating sections 1197 and 1198 as
25 sections 1198 and 1199, respectively; and

1 (2) by inserting after section 1196 the following
2 new section:

3 **“SEC. 1197. VOLUNTARY PARTICIPATION BY OTHER**
4 **HEALTH PLANS.**

5 “(a) AGREEMENT TO PARTICIPATE UNDER PRO-
6 GRAM.—

7 “(1) IN GENERAL.—Subject to paragraph (2),
8 under the program under this part the Secretary
9 shall be treated as having in effect an agreement
10 with a group health plan or health insurance issuer
11 offering group or individual health insurance cov-
12 erage (as such terms are defined in section 2791 of
13 the Public Health Service Act), with respect to a
14 price applicability period and a selected drug with
15 respect to such period—

16 “(A) in the case such selected drug fur-
17 nished or dispensed at a pharmacy or by mail
18 order service if coverage is provided under such
19 plan or coverage during such period for such se-
20 lected drug as so furnished or dispensed; and

21 “(B) in the case such selected drug fur-
22 nished or administered by a hospital, physician,
23 or other provider of services or supplier if cov-
24 erage is provided under such plan or coverage

1 during such period for such selected drug as so
2 furnished or administered.

3 “(2) OPTING OUT OF AGREEMENT.—The Sec-
4 retary shall not be treated as having in effect an
5 agreement under the program under this part with
6 a group health plan or health insurance issuer offer-
7 ing group or individual health insurance coverage
8 with respect to a price applicability period and a se-
9 lected drug with respect to such period if such a
10 plan or issuer affirmatively elects, through a process
11 specified by the Secretary, not to participate under
12 the program with respect to such period and drug.

13 “(b) PUBLICATION OF ELECTION.—With respect to
14 each price applicability period and each selected drug with
15 respect to such period, the Secretary and the Secretary
16 of Labor and the Secretary of the Treasury, as applicable,
17 shall make public a list of each group health plan and each
18 health insurance issuer offering group or individual health
19 insurance coverage, with respect to which coverage is pro-
20 vided under such plan or coverage for such drug, that has
21 elected under subsection (a) not to participate under the
22 program with respect to such period and drug.”.

23 (e) APPLICATION TO GROUP HEALTH PLANS AND
24 HEALTH INSURANCE COVERAGE.—

1 (1) PHSA.—Part D of title XXVII of the Pub-
2 lic Health Service Act (42 U.S.C. 300gg–111 et
3 seq.) is amended by adding at the end the following
4 new section:

5 **“SEC. 2799A–11. DRUG PRICE NEGOTIATION PROGRAM AND**
6 **APPLICATION OF MAXIMUM FAIR PRICES.**

7 “(a) IN GENERAL.—In the case of a group health
8 plan or health insurance issuer offering group or indi-
9 vidual health insurance coverage that is treated under sec-
10 tion 1197 of the Social Security Act as having in effect
11 an agreement with the Secretary under the Drug Price
12 Negotiation Program under part E of title XI of such Act,
13 with respect to a price applicability period (as defined in
14 section 1191(b) of such Act) and a selected drug (as de-
15 fined in section 1192(c) of such Act) with respect to such
16 period for which coverage is provided under such plan or
17 coverage—

18 “(1) the provisions of such part shall apply—

19 “(A) in the case the drug is furnished or
20 dispensed at a pharmacy or by a mail order
21 service, to such plan or coverage, and to the
22 participants, beneficiaries, and enrollees en-
23 rolled under such plan or coverage, during such
24 period, with respect to such selected drug, in
25 the same manner as such provisions apply to

1 prescription drug plans and MA–PD plans, and
2 to participants, beneficiaries, and enrollees en-
3 rolled under such prescription drug plans and
4 MA–PD plans during such period; and

5 “(B) in the case the drug is furnished or
6 administered by a hospital, physician, or other
7 provider of services or supplier, to such plan or
8 coverage, and to the participants, beneficiaries,
9 and enrollees enrolled under such plan or cov-
10 erage, and to hospitals, physicians, and other
11 providers of services and suppliers during such
12 period, with respect to such drug in the same
13 manner as such provisions apply to the Sec-
14 retary, to participants, beneficiaries, and enroll-
15 ees entitled to benefits under part A of title
16 XVIII or enrolled under part B of such title,
17 and to hospitals, physicians, and other pro-
18 viders and suppliers participating under title
19 XVIII during such period;

20 “(2) the plan or issuer shall apply any cost-
21 sharing responsibilities under such plan or coverage,
22 with respect to such selected drug, by substituting
23 an amount not more than the maximum fair price
24 negotiated under such part E of title XI for such
25 drug in lieu of the drug price upon which the cost-

1 sharing would have otherwise applied, and such cost-
2 sharing responsibilities with respect to such selected
3 drug may not exceed such maximum fair price; and

4 “(3) the Secretary shall apply the provisions of
5 such part E to such plan, issuer, and coverage, such
6 participants, beneficiaries, and enrollees so enrolled
7 in such plans and coverage, and such hospitals, phy-
8 sicians, and other providers and suppliers partici-
9 pating in such plans and coverage.

10 “(b) NOTIFICATION REGARDING NONPARTICIPATION
11 IN DRUG PRICE NEGOTIATION PROGRAM.—A group
12 health plan or a health insurance issuer offering group or
13 individual health insurance coverage shall publicly dis-
14 close, in a manner and in accordance with a process speci-
15 fied by the Secretary, any election made under section
16 1197 of the Social Security Act by such plan or issuer
17 to not participate in the Drug Price Negotiation Program
18 under part E of title XI of such Act with respect to a
19 selected drug (as defined in section 1192(c) of such Act)
20 for which coverage is provided under such plan or coverage
21 before the beginning of the plan year for which such elec-
22 tion was made.”.

23 (2) ERISA.—

24 (A) IN GENERAL.—Subpart B of part 7 of
25 subtitle B of title I of the Employee Retirement

1 Income Security Act of 1974 (29 U.S.C. 1185
2 et seq.) is amended by adding at the end the
3 following new section:

4 **“SEC. 726. DRUG PRICE NEGOTIATION PROGRAM AND AP-**
5 **PLICATION OF MAXIMUM FAIR PRICES.**

6 “(a) IN GENERAL.—In the case of a group health
7 plan or health insurance issuer offering group health in-
8 surance coverage that is treated under section 1197 of the
9 Social Security Act as having in effect an agreement with
10 the Secretary of Health and Human Services under the
11 Drug Price Negotiation Program under part E of title XI
12 of such Act, with respect to a price applicability period
13 (as defined in section 1191(b) of such Act) and a selected
14 drug (as defined in section 1192(c) of such Act) with re-
15 spect to such period for which coverage is provided under
16 such plan or coverage—

17 “(1) the provisions of such part shall apply, as
18 applicable—

19 “(A) in the case the drug is furnished or
20 dispensed at a pharmacy or by a mail order
21 service, to such plan or coverage, and to the
22 participants and beneficiaries enrolled under
23 such plan or coverage, during such period, with
24 respect to such selected drug, in the same man-
25 ner as such provisions apply to prescription

1 drug plans and MA–PD plans, and to partici-
2 pants and beneficiaries enrolled under such pre-
3 scription drug plans and MA–PD plans during
4 such period; and

5 “(B) in the case the drug is furnished or
6 administered by a hospital, physician, or other
7 provider of services or supplier, to the group
8 health plan or coverage offered by an issuer, to
9 the participants and beneficiaries enrolled
10 under such plans or coverage, and to hospitals,
11 physicians, and other providers of services and
12 suppliers during such period, with respect to
13 such drug in the same manner as such provi-
14 sions apply to the Secretary of Health and
15 Human Services, to participants and bene-
16 ficiaries entitled to benefits under part A of
17 title XVIII or enrolled under part B of such
18 title, and to hospitals, physicians, and other
19 providers and suppliers participating under title
20 XVIII during such period;

21 “(2) the plan or issuer shall apply any cost-
22 sharing responsibilities under such plan or coverage,
23 with respect to such selected drug, by substituting
24 an amount not more than the maximum fair price
25 negotiated under such part E of title XI for such

1 drug in lieu of the drug price upon which the cost-
2 sharing would have otherwise applied, and such cost-
3 sharing responsibilities with respect to such selected
4 drug may not exceed such maximum fair price; and

5 “(3) the Secretary shall apply the provisions of
6 such part E to such plan, issuer, and coverage, and
7 such participants and beneficiaries so enrolled in
8 such plans.

9 “(b) NOTIFICATION REGARDING NONPARTICIPATION
10 IN DRUG PRICE NEGOTIATION PROGRAM.—A group
11 health plan or a health insurance issuer offering group
12 health insurance coverage shall publicly disclose in a man-
13 ner and in accordance with a process specified by the Sec-
14 retary any election made under section 1197 of the Social
15 Security Act by the plan or issuer to not participate in
16 the Drug Price Negotiation Program under part E of title
17 XI of such Act with respect to a selected drug (as defined
18 in section 1192(c) of such Act) for which coverage is pro-
19 vided under such plan or coverage before the beginning
20 of the plan year for which such election was made.”.

21 (B) APPLICATION TO RETIREE AND CER-
22 TAIN SMALL GROUP HEALTH PLANS.—Section
23 732(a) of the Employee Retirement Income Se-
24 curity Act of 1974 (29 U.S.C. 1191a(a)) is

1 amended by striking “section 711” and insert-
2 ing “sections 711 and 726”.

3 (C) CLERICAL AMENDMENT.—The table of
4 contents in section 1 of such Act is amended by
5 inserting after the item relating to section 725
6 the following new item:

“Sec. 726. Drug Price Negotiation Program and application of maximum fair
prices.”.

7 (3) IRC.—

8 (A) IN GENERAL.—Subchapter B of chap-
9 ter 100 of the Internal Revenue Code of 1986
10 is amended by adding at the end the following
11 new section:

12 **“SEC. 9826. DRUG PRICE NEGOTIATION PROGRAM AND AP-**
13 **PLICATION OF MAXIMUM FAIR PRICES.**

14 “(a) IN GENERAL.—In the case of a group health
15 plan that is treated under section 1197 of the Social Secu-
16 rity Act as having in effect an agreement with the Sec-
17 retary of Health and Human Services under the Drug
18 Price Negotiation Program under part E of title XI of
19 such Act, with respect to a price applicability period (as
20 defined in section 1191(b) of such Act) and a selected
21 drug (as defined in section 1192(c) of such Act) with re-
22 spect to such period for which coverage is provided under
23 such plan—

1 “(1) the provisions of such part shall apply, as
2 applicable—

3 “(A) if coverage of such selected drug is
4 provided under such plan if the drug is fur-
5 nished or dispensed at a pharmacy or by a mail
6 order service, to the plan, and to the partici-
7 pants and beneficiaries enrolled under such
8 plan during such period, with respect to such
9 selected drug, in the same manner as such pro-
10 visions apply to prescription drug plans and
11 MA–PD plans, and to participants and bene-
12 ficiaries enrolled under such prescription drug
13 plans and MA–PD plans during such period;
14 and

15 “(B) if coverage of such selected drug is
16 provided under such plan if the drug is fur-
17 nished or administered by a hospital, physician,
18 or other provider of services or supplier, to the
19 plan, to the participants and beneficiaries en-
20 rolled under such plan, and to hospitals, physi-
21 cians, and other providers of services and sup-
22 pliers during such period, with respect to such
23 drug in the same manner as such provisions
24 apply to the Secretary of Health and Human
25 Services, to participants and beneficiaries enti-

1 tled to benefits under part A of title XVIII or
2 enrolled under part B of such title, and to hos-
3 pitals, physicians, and other providers and sup-
4 pliers participating under title XVIII during
5 such period;

6 “(2) the plan shall apply any cost-sharing re-
7 sponsibilities under such plan, with respect to such
8 selected drug, by substituting an amount not more
9 than the maximum fair price negotiated under such
10 part E of title XI for such drug in lieu of the drug
11 price upon which the cost-sharing would have other-
12 wise applied, and such cost-sharing responsibilities
13 with respect to such selected drug may not exceed
14 such maximum fair price; and

15 “(3) the Secretary shall apply the provisions of
16 such part E to such plan and such participants and
17 beneficiaries so enrolled in such plan.

18 “(b) NOTIFICATION REGARDING NONPARTICIPATION
19 IN DRUG PRICE NEGOTIATION PROGRAM.—A group
20 health plan shall publicly disclose in a manner and in ac-
21 cordance with a process specified by the Secretary any
22 election made under section 1197 of the Social Security
23 Act by the plan to not participate in the Drug Price Nego-
24 tiation Program under part E of title XI of such Act with
25 respect to a selected drug (as defined in section 1192(c))

1 of such Act) for which coverage is provided under such
2 plan before the beginning of the plan year for which such
3 election was made.”.

4 (B) APPLICATION TO RETIREE AND CER-
5 TAIN SMALL GROUP HEALTH PLANS.—Section
6 9831(a)(2) of the Internal Revenue Code of
7 1986 is amended by inserting “other than with
8 respect to section 9826,” before “any group
9 health plan”.

10 (C) CLERICAL AMENDMENT.—The table of
11 sections for subchapter B of chapter 100 of the
12 Internal Revenue Code of 1986 is amended by
13 adding at the end the following new item:

“Sec. 9826. Drug Price Negotiation Program and application of maximum fair
prices.”.

14 **SEC. 102. REQUIRING CONSIDERATION OF AVERAGE INTER-**
15 **NATIONAL MARKET PRICE UNDER DRUG**
16 **PRICE NEGOTIATION PROGRAM.**

17 (a) IN GENERAL.—Section 1194(e) of the Social Se-
18 curity Act (42 U.S.C. 1320f–3(e)) is amended by adding
19 at the end the following new paragraph:

20 “(3) AVERAGE INTERNATIONAL MARKET
21 PRICE.—

22 “(A) IN GENERAL.—The average price
23 (which shall be the net average price, if prac-
24 ticable, and volume-weighted, if practicable) for

1 a unit (as defined in subparagraph (C)) of such
2 drug for sales of such drug (calculated across
3 different dosage forms and strengths of the
4 drug and not based on the specific formulation
5 or package size or package type), as computed
6 (as of the date of publication of such drug as
7 a selected drug under section 1192(a)) in all
8 countries described in clause (ii) of subpara-
9 graph (B) that are applicable countries (as de-
10 scribed in clause (i) of such subparagraph) with
11 respect to such drug.

12 “(B) APPLICABLE COUNTRIES.—

13 “(i) IN GENERAL.—For purposes of
14 subparagraph (A), a country described in
15 clause (ii) is an applicable country de-
16 scribed in this clause with respect to a
17 drug if there is available an average price
18 for any unit for the drug for sales of such
19 drug in such country.

20 “(ii) COUNTRIES DESCRIBED.—For
21 purposes of this paragraph, the following
22 are countries described in this clause:

23 “(I) Australia.

24 “(II) Canada.

25 “(III) France.

1 “(IV) Germany.

2 “(V) Japan.

3 “(VI) The United Kingdom.

4 “(C) UNIT DEFINED.—For purposes of
5 this paragraph, term ‘unit’ means, with respect
6 to a drug, the lowest identifiable quantity (such
7 as a capsule or tablet, milligram of molecules,
8 or grams) of the drug that is dispensed.”.

9 (b) EFFECTIVE DATE.—The amendment made by
10 subsection (a) shall apply with respect to negotiations
11 under the Drug Price Negotiation Program under part E
12 of title XI of the Social Security Act (42 U.S.C. 1320f
13 et seq.) for initial price applicability years beginning on
14 or after January 1, 2028, and renegotiations under such
15 program for years beginning on or after such date.

16 **SEC. 103. REPEALING CERTAIN CHANGES TO THE DRUG**
17 **PRICE NEGOTIATION PROGRAM MADE BY**
18 **PUBLIC LAW 119–21.**

19 Section 71203 of the Act titled “An Act to provide
20 for reconciliation pursuant to title II of H. Con. Res. 14”
21 (Public Law 119–21) is repealed, and the provisions of
22 law amended by such section are hereby restored as if such
23 section had not been enacted into law.

1 **TITLE II—PRESCRIPTION DRUG**
2 **INFLATION REBATES**

3 **SEC. 201. APPLICATION OF PRESCRIPTION DRUG INFLA-**
4 **TION REBATES TO DRUGS FURNISHED IN**
5 **THE COMMERCIAL MARKET.**

6 (a) PART B DRUGS.—

7 (1) APPLICATION OF PRESCRIPTION DRUG IN-
8 FLATION REBATES TO DRUGS FURNISHED IN THE
9 COMMERCIAL MARKET.—Section 1847A(i) of the So-
10 cial Security Act (42 U.S.C. 1395w–3a(i)) is amend-
11 ed—

12 (A) in paragraph (1)(A)(i), by striking
13 “units” and inserting “billing units”;

14 (B) in paragraph (2)(A), by striking “for
15 which payment is made under this part” and
16 inserting “that would be payable under this
17 part if such drug were furnished to an indi-
18 vidual enrolled under this part”; and

19 (C) in paragraph (3)—

20 (i) in subparagraph (A)(i), by striking
21 “units” and inserting “billing units”; and

22 (ii) by striking subparagraph (B) and
23 inserting the following:

24 “(B) TOTAL NUMBER OF BILLING
25 UNITS.—For purposes of subparagraph (A)(i),

1 the total number of billing units with respect to
2 a part B rebatable drug is determined as fol-
3 lows:

4 “(i) Determine the total number of
5 units equal to—

6 “(I) the total number of units, as
7 reported under subsection (c)(1)(B)
8 for each National Drug Code of such
9 drug during the calendar quarter that
10 is two calendar quarters prior to the
11 calendar quarter as described in sub-
12 paragraph (A), minus

13 “(II) the total number of units
14 with respect to each National Drug
15 Code of such drug for which payment
16 was made under a State plan under
17 title XIX (or waiver of such plan), as
18 reported by States under section
19 1927(b)(2)(A) for the rebate period
20 that is the same calendar quarter as
21 described in subclause (I).

22 “(ii) Convert the units determined
23 under clause (i) to billing units for the bill-
24 ing and payment code of such drug, using
25 a methodology similar to the methodology

1 used under this section, by dividing the
2 units determined under clause (i) for each
3 National Drug Code of such drug by the
4 billing unit for the billing and payment
5 code of such drug.

6 “(iii) Compute the sum of the billing
7 units for each National Drug Code of such
8 drug in clause (ii).”.

9 (2) EFFECTIVE DATE.—The amendments made
10 by this subsection shall apply with respect to cal-
11 endar quarters beginning after the date of the enact-
12 ment of this Act.

13 (b) COVERED PART D DRUGS.—

14 (1) APPLICATION OF PRESCRIPTION DRUG IN-
15 FLATION REBATES TO DRUGS FURNISHED IN THE
16 COMMERCIAL MARKET.—Section 1860D–14B of the
17 Social Security Act (42 U.S.C. 1395w–114b) is
18 amended—

19 (A) in subsection (b)—

20 (i) in paragraph (1)—

21 (I) in subparagraph (A)(i), by
22 striking “the total number of units”
23 and all that follows through the semi-
24 colon and inserting the following: “the
25 total number of units that are used to

1 calculate the average manufacturer
2 price of such dosage form and
3 strength with respect to such part D
4 rebatable drug, as reported by the
5 manufacturer of such drug under sec-
6 tion 1927 for each month, with re-
7 spect to such period;” and

8 (II) by striking subparagraph (B)
9 and inserting the following:

10 “(B) EXCLUDED UNITS.—For purposes of
11 subparagraph (A)(i), the Secretary shall exclude
12 from the total number of units for a dosage
13 form and strength with respect to a part D
14 rebatable drug, with respect to an applicable pe-
15 riod, the following:

16 “(i) Units of each dosage form and
17 strength of such part D rebatable drug for
18 which payment was made under a State
19 plan under title XIX (or waiver of such
20 plan), as reported by States under section
21 1927(b)(2)(A).

22 “(ii) Units of each dosage form and
23 strength of such part D rebatable drug for
24 which a rebate is paid under section
25 1847A(i).

1 “(iii) Beginning with plan year 2026,
2 units of each dosage form and strength of
3 such part D rebatable drug for which the
4 manufacturer provides a discount under
5 the program under section 340B of the
6 Public Health Service Act.”; and

7 (ii) in paragraph (6), by striking “IN-
8 FORMATION” and all that follows through
9 “rebatable covered part D drug dispensed”
10 and inserting the following: “AMP RE-
11 PORTS.—The Secretary shall provide for a
12 method and process under which, in the
13 case of a manufacturer of a part D
14 rebatable drug that submits revisions to in-
15 formation submitted under section 1927 by
16 the manufacturer with respect to such
17 drug”; and

18 (B) by striking subsection (d) and insert-
19 ing the following:

20 “(d) INFORMATION.—For purposes of carrying out
21 this section, the Secretary shall use information submitted
22 by manufacturers under section 1927(b)(3) and informa-
23 tion submitted by States under section 1927(b)(2)(A).”.

24 (2) EFFECTIVE DATE.—The amendments made
25 by this subsection shall apply with respect to appli-

1 cable periods (as defined in section 1860D–
2 14B(g)(7) of the Social Security Act (42 U.S.C.
3 1395w–114b(g)(7))) beginning after the date of the
4 enactment of this Act.

5 **TITLE III—OUT-OF-POCKET LIM-**
6 **ITS FOR PRESCRIPTION**
7 **DRUGS**

8 **SEC. 301. ESTABLISHING AN OUT-OF-POCKET LIMIT ON EX-**
9 **PENDITURES FOR PRESCRIPTION DRUGS**
10 **UNDER GROUP HEALTH PLANS AND GROUP**
11 **AND INDIVIDUAL HEALTH INSURANCE COV-**
12 **ERAGE.**

13 (a) PHSA.—Title XXVII of the Public Health Serv-
14 ice Act (42 U.S.C. 300gg et seq.), as amended by section
15 101, is further amended—

16 (1) in section 2707, by adding at the end the
17 following new subsection:

18 “(e) SUNSET.—The preceding provisions of this sec-
19 tion shall not apply with respect to plan years beginning
20 on or after January 1, 2027.”; and

21 (2) in part D, by adding at the end the fol-
22 lowing new section:

23 **“SEC. 2799A–12. COMPREHENSIVE COVERAGE.**

24 **“(a) COVERAGE FOR ESSENTIAL HEALTH BENEFITS**
25 **PACKAGE.—A health insurance issuer that offers health**

1 insurance coverage in the individual or small group market
2 shall ensure that such coverage includes the essential
3 health benefits package required under section 1302(a) of
4 the Patient Protection and Affordable Care Act.

5 “(b) COST-SHARING LIMITATION.—

6 “(1) IN GENERAL.—A group health plan and a
7 health insurance issuer offering group or individual
8 health insurance coverage shall ensure that—

9 “(A) any annual cost-sharing imposed
10 under the plan or coverage (including any such
11 cost-sharing so imposed with respect to pre-
12 scription drugs) does not exceed the dollar
13 amounts specified in paragraph (2); and

14 “(B) any annual cost-sharing imposed
15 under the plan or coverage with respect to pre-
16 scription drugs does not exceed the dollar
17 amounts specified in paragraph (3).

18 “(2) LIMITATION ON OVERALL OUT-OF-POCKET
19 COST-SHARING.—For purposes of paragraph (1)(A),
20 the dollar amounts specified in this paragraph are
21 the following:

22 “(A) With respect to self-only coverage—

23 “(i) for plan years beginning in 2027,
24 the dollar amount in effect under section
25 1302(c)(1) of the Patient Protection and

1 Affordable Care Act for such coverage for
2 plan years beginning in 2014, increased by
3 an amount equal to the product of that
4 amount and the premium adjustment per-
5 centage specified in paragraph (4) of such
6 section for the calendar year; and

7 “(ii) for plan years beginning in 2028
8 or a subsequent year, the dollar amount in
9 effect under this subparagraph for plan
10 years beginning in 2027, increased by an
11 amount equal to the product of that
12 amount the premium adjustment percent-
13 age specified in paragraph (4) for the cal-
14 endar year.

15 “(B) With respect to coverage other than
16 self-only coverage, for plan years beginning in
17 2027 or a subsequent year, twice the amount in
18 effect under subparagraph (A) for such plan
19 year.

20 If the amount of any increase under subparagraph
21 (A) is not a multiple of \$50, such increase shall be
22 rounded to the next lowest multiple of \$50.

23 “(3) LIMITATION ON PRESCRIPTION DRUG OUT-
24 OF-POCKET COST-SHARING.—For purposes of para-

1 graph (1)(B), the dollar amounts specified in this
2 paragraph are the following:

3 “(A) With respect to self-only coverage—

4 “(i) for plan years beginning in 2027,
5 \$2,000; and

6 “(ii) for plan years beginning in 2028
7 or a subsequent year, the dollar amount in
8 effect under this subparagraph for plan
9 years beginning in 2027, increased by an
10 amount equal to the product of that
11 amount and the premium adjustment per-
12 centage under paragraph (4) for the cal-
13 endar year.

14 “(B) With respect to coverage other than
15 self-only coverage, for plan years beginning in
16 2027 or a subsequent year, twice the amount in
17 effect under subparagraph (A) for such plan
18 year.

19 If the amount of any increase under subparagraph
20 (A) is not a multiple of \$50, such increase shall be
21 rounded to the next lowest multiple of \$50.

22 “(4) PREMIUM ADJUSTMENT PERCENTAGE.—

23 For purposes of paragraphs (2)(A)(ii) and (3)(A)(ii),
24 the premium adjustment percentage for any cal-
25 endar year is the percentage (if any) by which the

1 average per capita premium for health insurance
2 coverage in the United States for the preceding cal-
3 endar year (as estimated by the Secretary no later
4 than October 1 of such preceding calendar year) ex-
5 ceeds such average per capita premium for 2026 (as
6 determined by the Secretary).

7 “(5) COST-SHARING.—In this section:

8 “(A) IN GENERAL.—The term ‘cost-shar-
9 ing’ includes—

10 “(i) deductibles, coinsurance, copay-
11 ments, or similar charges; and

12 “(ii) any other expenditure required of
13 an insured individual which is a qualified
14 medical expense (within the meaning of
15 section 223(d)(2) of the Internal Revenue
16 Code of 1986) with respect to essential
17 health benefits covered under the plan or
18 coverage.

19 “(B) EXCEPTIONS.—Such term does not
20 include premiums, balance billing amounts for
21 non-network providers, or spending for non-cov-
22 ered services.

23 “(6) IMPLEMENTATION.—The Secretary may
24 implement the provisions of this subsection by sub-
25 regulatory guidance, interim final rule, or otherwise.

1 “(c) CHILD-ONLY PLANS.—If a health insurance
2 issuer offers health insurance coverage in any level of cov-
3 erage specified under section 1302(d) of the Patient Pro-
4 tection and Affordable Care Act, the issuer shall also offer
5 such coverage in that level as a plan in which the only
6 enrollees are individuals who, as of the beginning of a plan
7 year, have not attained the age of 21.

8 “(d) DENTAL ONLY.—This section shall not apply to
9 a plan described in section 1311(d)(2)(B)(ii) of the Pa-
10 tient Protection and Affordable Care Act.”.

11 (b) ERISA.—

12 (1) IN GENERAL.—Subpart B of part 7 of sub-
13 title B of title I of the Employee Retirement Income
14 Security Act of 1974 (29 U.S.C. 1185 et seq.), as
15 amended by section 101, is further amended by add-
16 ing at the end the following new section:

17 **“SEC. 727. COMPREHENSIVE COVERAGE.**

18 “(a) COVERAGE FOR ESSENTIAL HEALTH BENEFITS
19 PACKAGE.—A health insurance issuer that offers health
20 insurance coverage in the small group market shall ensure
21 that such coverage includes the essential health benefits
22 package required under section 1302(a) of the Patient
23 Protection and Affordable Care Act.

24 “(b) COST-SHARING LIMITATION.—

1 “(1) IN GENERAL.—A group health plan and a
2 health insurance issuer offering group health insur-
3 ance coverage shall ensure that—

4 “(A) any annual cost-sharing imposed
5 under the plan or coverage (including any such
6 cost-sharing so imposed with respect to pre-
7 scription drugs) does not exceed the dollar
8 amounts specified in paragraph (2); and

9 “(B) any annual cost-sharing imposed
10 under the plan or coverage with respect to pre-
11 scription drugs does not exceed the dollar
12 amounts specified in paragraph (3).

13 “(2) LIMITATION ON OVERALL OUT-OF-POCKET
14 COST-SHARING.—For purposes of paragraph (1)(A),
15 the dollar amounts specified in this paragraph are
16 the following:

17 “(A) With respect to self-only coverage—

18 “(i) for plan years beginning in 2027,
19 the dollar amount in effect under section
20 1302(c)(1) of the Patient Protection and
21 Affordable Care Act for such coverage for
22 plan years beginning in 2014, increased by
23 an amount equal to the product of that
24 amount and the premium adjustment per-

1 centage specified in paragraph (4) of such
2 section for the calendar year; and

3 “(ii) for plan years beginning in 2028
4 or a subsequent year, the dollar amount in
5 effect under this subparagraph for plan
6 years beginning in 2027, increased by an
7 amount equal to the product of that
8 amount the premium adjustment percent-
9 age specified in paragraph (4) for the cal-
10 endar year.

11 “(B) With respect to coverage other than
12 self-only coverage, for plan years beginning in
13 2027 or a subsequent year, twice the amount in
14 effect under subparagraph (A) for such plan
15 year.

16 If the amount of any increase under subparagraph
17 (A) is not a multiple of \$50, such increase shall be
18 rounded to the next lowest multiple of \$50.

19 “(3) LIMITATION ON PRESCRIPTION DRUG OUT-
20 OF-POCKET COST-SHARING.—For purposes of para-
21 graph (1)(B), the dollar amounts specified in this
22 paragraph are the following:

23 “(A) With respect to self-only coverage—

24 “(i) for plan years beginning in 2027,
25 \$2,000; and

1 “(ii) for plan years beginning in 2028
2 or a subsequent year, the dollar amount in
3 effect under this subparagraph for plan
4 years beginning in 2027, increased by an
5 amount equal to the product of that
6 amount and the premium adjustment per-
7 centage under paragraph (4) for the cal-
8 endar year.

9 “(B) With respect to coverage other than
10 self-only coverage, for plan years beginning in
11 2027 or a subsequent year, twice the amount in
12 effect under subparagraph (A) for such plan
13 year.

14 If the amount of any increase under subparagraph
15 (A) is not a multiple of \$50, such increase shall be
16 rounded to the next lowest multiple of \$50.

17 “(4) PREMIUM ADJUSTMENT PERCENTAGE.—
18 For purposes of paragraphs (2)(A)(ii) and (3)(A)(ii),
19 the premium adjustment percentage for any cal-
20 endar year is the percentage (if any) by which the
21 average per capita premium for health insurance
22 coverage in the United States for the preceding cal-
23 endar year (as estimated by the Secretary no later
24 than October 1 of such preceding calendar year) ex-

1 ceeds such average per capita premium for 2026 (as
2 determined by the Secretary).

3 “(5) COST-SHARING.—In this section:

4 “(A) IN GENERAL.—The term ‘cost-shar-
5 ing’ includes—

6 “(i) deductibles, coinsurance, copay-
7 ments, or similar charges; and

8 “(ii) any other expenditure required of
9 an insured individual which is a qualified
10 medical expense (within the meaning of
11 section 223(d)(2) of the Internal Revenue
12 Code of 1986) with respect to essential
13 health benefits covered under the plan or
14 coverage.

15 “(B) EXCEPTIONS.—Such term does not
16 include premiums, balance billing amounts for
17 non-network providers, or spending for non-cov-
18 ered services.

19 “(6) IMPLEMENTATION.—The Secretary may
20 implement the provisions of this subsection by sub-
21 regulatory guidance, interim final rule, or otherwise.

22 “(c) CHILD-ONLY PLANS.—If a health insurance
23 issuer offers health insurance coverage in any level of cov-
24 erage specified under section 1302(d) of the Patient Pro-
25 tection and Affordable Care Act, the issuer shall also offer

1 such coverage in that level as a plan in which the only
2 enrollees are individuals who, as of the beginning of a plan
3 year, have not attained the age of 21.

4 “(d) DENTAL ONLY.—This section shall not apply to
5 a plan described in section 1311(d)(2)(B)(ii) of the Pa-
6 tient Protection and Affordable Care Act.”.

7 (2) CLERICAL AMENDMENT.—The table of con-
8 tents in section 1 of such Act is amended by insert-
9 ing after the item relating to section 726 (as in-
10 serted by section 101) the following new item:

“Sec. 727. Comprehensive coverage.”.

11 (c) IRC.—

12 (1) IN GENERAL.—Subchapter B of chapter
13 100 of the Internal Revenue Code of 1986, as
14 amended by section 101, is further amended by add-
15 ing at the end the following new section:

16 **“SEC. 9827. COMPREHENSIVE COVERAGE.**

17 “(a) COST-SHARING LIMITATION.—

18 “(1) IN GENERAL.—A group health plan shall
19 ensure that—

20 “(A) any annual cost-sharing imposed
21 under the plan (including any such cost-sharing
22 so imposed with respect to prescription drugs)
23 does not exceed the dollar amounts specified in
24 paragraph (2); and

1 “(B) any annual cost-sharing imposed
2 under the plan with respect to prescription
3 drugs does not exceed the dollar amounts speci-
4 fied in paragraph (3).

5 “(2) LIMITATION ON OVERALL OUT-OF-POCKET
6 COST-SHARING.—For purposes of paragraph (1)(A),
7 the dollar amounts specified in this paragraph are
8 the following:

9 “(A) With respect to self-only coverage—

10 “(i) for plan years beginning in 2027,
11 the dollar amount in effect under section
12 1302(c)(1) of the Patient Protection and
13 Affordable Care Act for such coverage for
14 plan years beginning in 2014, increased by
15 an amount equal to the product of that
16 amount and the premium adjustment per-
17 centage specified in paragraph (4) of such
18 section for the calendar year; and

19 “(ii) for plan years beginning in 2028
20 or a subsequent year, the dollar amount in
21 effect under this subparagraph for plan
22 years beginning in 2027, increased by an
23 amount equal to the product of that
24 amount the premium adjustment percent-

1 age specified in paragraph (4) for the cal-
2 endar year.

3 “(B) With respect to coverage other than
4 self-only coverage, for plan years beginning in
5 2027 or a subsequent year, twice the amount in
6 effect under subparagraph (A) for such plan
7 year.

8 If the amount of any increase under subparagraph
9 (A) is not a multiple of \$50, such increase shall be
10 rounded to the next lowest multiple of \$50.

11 “(3) LIMITATION ON PRESCRIPTION DRUG OUT-
12 OF-POCKET COST-SHARING.—For purposes of para-
13 graph (1)(B), the dollar amounts specified in this
14 paragraph are the following:

15 “(A) With respect to self-only coverage—

16 “(i) for plan years beginning in 2027,
17 \$2,000; and

18 “(ii) for plan years beginning in 2028
19 or a subsequent year, the dollar amount in
20 effect under this subparagraph for plan
21 years beginning in 2027, increased by an
22 amount equal to the product of that
23 amount and the premium adjustment per-
24 centage under paragraph (4) for the cal-
25 endar year.

1 “(B) With respect to coverage other than
2 self-only coverage, for plan years beginning in
3 2027 or a subsequent year, twice the amount in
4 effect under subparagraph (A) for such plan
5 year.

6 If the amount of any increase under subparagraph
7 (A) is not a multiple of \$50, such increase shall be
8 rounded to the next lowest multiple of \$50.

9 “(4) PREMIUM ADJUSTMENT PERCENTAGE.—
10 For purposes of paragraphs (2)(A)(ii) and (3)(A)(ii),
11 the premium adjustment percentage for any cal-
12 endar year is the percentage (if any) by which the
13 average per capita premium for health insurance
14 coverage in the United States for the preceding cal-
15 endar year (as estimated by the Secretary no later
16 than October 1 of such preceding calendar year) ex-
17 ceeds such average per capita premium for 2026 (as
18 determined by the Secretary).

19 “(5) COST-SHARING.—In this section:

20 “(A) IN GENERAL.—The term ‘cost-shar-
21 ing’ includes—

22 “(i) deductibles, coinsurance, copay-
23 ments, or similar charges; and

24 “(ii) any other expenditure required of
25 an insured individual which is a qualified

1 medical expense (within the meaning of
2 section 223(d)(2) of the Internal Revenue
3 Code of 1986) with respect to essential
4 health benefits covered under the plan.

5 “(B) EXCEPTIONS.—Such term does not
6 include premiums, balance billing amounts for
7 non-network providers, or spending for non-cov-
8 ered services.

9 “(6) IMPLEMENTATION.—The Secretary may
10 implement the provisions of this subsection by sub-
11 regulatory guidance, interim final rule, or otherwise.

12 “(b) DENTAL ONLY.—This section shall not apply to
13 a plan described in section 1311(d)(2)(B)(ii) of the Pa-
14 tient Protection and Affordable Care Act.”.

15 (2) CLERICAL AMENDMENT.—The table of sec-
16 tions for subchapter B of chapter 100 of the Inter-
17 nal Revenue Code of 1986, as amended by section
18 101, is further amended by adding at the end the
19 following new item:

“Sec. 9827. Comprehensive coverage.”.

20 (d) CONFORMING AMENDMENTS.—The Patient Pro-
21 tection and Affordable Care Act (Public Law 111–148)
22 is amended—

23 (1) in section 1302—

1 (A) in subsection (a)(2), by inserting “with
2 respect to plan years beginning before January
3 1, 2027,” before “limits cost-sharing”; and

4 (B) in subsection (e)(1)(B)(i)—

5 (i) by inserting “(or, with respect to
6 plan years beginning on or after January
7 1, 2027, in effect under section 2799A–
8 12(b)(1)(A)) of the Public Health Service
9 Act)” after “subsection (c)(1)”; and

10 (ii) by inserting “and except, with re-
11 spect to plan years beginning on or after
12 January 1, 2027, in the case of an indi-
13 vidual who has incurred cost-sharing ex-
14 penses with respect to prescription drugs
15 in an amount equal to the annual limita-
16 tion in effect under section 2799A–
17 12(b)(1)(B) of such Act, for benefits con-
18 sisting of prescription drugs” after “sec-
19 tion 2713”; and

20 (2) in section 1402(c)(1)(A), by inserting “(or,
21 with respect to plan years beginning on or after Jan-
22 uary 1, 2027, the applicable out-of-pocket limit
23 under section 2799A–12(b)(1)(A) of the Public
24 Health Service Act)” after “section 1302(c)(1)”.

1 (e) EFFECTIVE DATE.—The amendments made by
2 this section shall apply with respect to plan years begin-
3 ning on or after January 1, 2027.

4 **SEC. 302. REQUIREMENTS WITH RESPECT TO COST-SHAR-**
5 **ING FOR INSULIN PRODUCTS.**

6 (a) PHSA.—Part D of title XXVII of the Public
7 Health Service Act (42 U.S.C. 300gg–111 et seq.), as
8 amended by sections 101 and 301, is further amended by
9 adding at the end the following new section:

10 **“SEC. 2799A–13. REQUIREMENTS WITH RESPECT TO COST-**
11 **SHARING FOR CERTAIN INSULIN PRODUCTS.**

12 “(a) IN GENERAL.—For plan years beginning on or
13 after January 1, 2027, a group health plan or health in-
14 surance issuer offering group or individual health insur-
15 ance coverage shall provide coverage of selected insulin
16 products, and with respect to such products, shall not—

17 “(1) apply any deductible; or

18 “(2) impose any cost-sharing in excess of the
19 lesser of, per 30-day supply—

20 “(A) \$35; or

21 “(B) the amount equal to 25 percent of
22 the negotiated price of the selected insulin prod-
23 uct net of all price concessions received by or on
24 behalf of the plan or coverage, including price
25 concessions received by or on behalf of third-

1 party entities providing services to the plan or
2 coverage, such as pharmacy benefit manage-
3 ment services.

4 “(b) DEFINITIONS.—In this section:

5 “(1) SELECTED INSULIN PRODUCTS.—The term
6 ‘selected insulin products’ means at least one of each
7 dosage form (such as vial, pump, or inhaler dosage
8 forms) of each different type (such as rapid-acting,
9 short-acting, intermediate-acting, long-acting, ultra
10 long-acting, and premixed) of insulin (as defined
11 below), when available, as selected by the group
12 health plan or health insurance issuer.

13 “(2) INSULIN DEFINED.—The term ‘insulin’
14 means insulin that is licensed under subsection (a)
15 or (k) of section 351 and continues to be marketed
16 under such section, including any insulin product
17 that has been deemed to be licensed under section
18 351(a) pursuant to section 7002(e)(4) of the Bio-
19 logics Price Competition and Innovation Act of 2009
20 (Public Law 111–148) and continues to be marketed
21 pursuant to such licensure.

22 “(c) OUT-OF-NETWORK PROVIDERS.—Nothing in
23 this section requires a plan or issuer that has a network
24 of providers to provide benefits for selected insulin prod-
25 ucts described in this section that are delivered by an out-

1 of-network provider, or precludes a plan or issuer that has
2 a network of providers from imposing higher cost-sharing
3 than the levels specified in subsection (a) for selected insu-
4 lin products described in this section that are delivered
5 by an out-of-network provider.

6 “(d) RULE OF CONSTRUCTION.—Subsection (a) shall
7 not be construed to require coverage of, or prevent a group
8 health plan or health insurance coverage from imposing
9 cost-sharing other than the levels specified in subsection
10 (a) on, insulin products that are not selected insulin prod-
11 ucts, to the extent that such coverage is not otherwise re-
12 quired and such cost-sharing is otherwise permitted under
13 Federal and applicable State law.

14 “(e) APPLICATION OF COST-SHARING TOWARDS
15 DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any
16 cost-sharing payments made pursuant to subsection (a)(2)
17 shall be counted toward any deductible or out-of-pocket
18 maximum that applies under the plan or coverage.”.

19 (b) ERISA.—

20 (1) IN GENERAL.—Subpart B of part 7 of sub-
21 title B of title I of the Employee Retirement Income
22 Security Act of 1974 (29 U.S.C. 1185 et seq.), as
23 amended by sections 101 and 301, is further amend-
24 ed by adding at the end the following new section:

1 **“SEC. 728. REQUIREMENTS WITH RESPECT TO COST-SHAR-**
2 **ING FOR CERTAIN INSULIN PRODUCTS.**

3 “(a) IN GENERAL.—For plan years beginning on or
4 after January 1, 2027, a group health plan or health in-
5 surance issuer offering group health insurance coverage
6 shall provide coverage of selected insulin products, and
7 with respect to such products, shall not—

8 “(1) apply any deductible; or

9 “(2) impose any cost-sharing in excess of the
10 lesser of, per 30-day supply—

11 “(A) \$35; or

12 “(B) the amount equal to 25 percent of
13 the negotiated price of the selected insulin prod-
14 uct net of all price concessions received by or on
15 behalf of the plan or coverage, including price
16 concessions received by or on behalf of third-
17 party entities providing services to the plan or
18 coverage, such as pharmacy benefit manage-
19 ment services.

20 “(b) DEFINITIONS.—In this section:

21 “(1) SELECTED INSULIN PRODUCTS.—The term
22 ‘selected insulin products’ means at least one of each
23 dosage form (such as vial, pump, or inhaler dosage
24 forms) of each different type (such as rapid-acting,
25 short-acting, intermediate-acting, long-acting, ultra
26 long-acting, and premixed) of insulin (as defined

1 below), when available, as selected by the group
2 health plan or health insurance issuer.

3 “(2) INSULIN DEFINED.—The term ‘insulin’
4 means insulin that is licensed under subsection (a)
5 or (k) of section 351 of the Public Health Service
6 Act (42 U.S.C. 262) and continues to be marketed
7 under such section, including any insulin product
8 that has been deemed to be licensed under section
9 351(a) of such Act pursuant to section 7002(e)(4)
10 of the Biologics Price Competition and Innovation
11 Act of 2009 (Public Law 111–148) and continues to
12 be marketed pursuant to such licensure.

13 “(c) OUT-OF-NETWORK PROVIDERS.—Nothing in
14 this section requires a plan or issuer that has a network
15 of providers to provide benefits for selected insulin prod-
16 ucts described in this section that are delivered by an out-
17 of-network provider, or precludes a plan or issuer that has
18 a network of providers from imposing higher cost-sharing
19 than the levels specified in subsection (a) for selected insu-
20 lin products described in this section that are delivered
21 by an out-of-network provider.

22 “(d) RULE OF CONSTRUCTION.—Subsection (a) shall
23 not be construed to require coverage of, or prevent a group
24 health plan or health insurance coverage from imposing
25 cost-sharing other than the levels specified in subsection

1 (a) on, insulin products that are not selected insulin prod-
2 ucts, to the extent that such coverage is not otherwise re-
3 quired and such cost-sharing is otherwise permitted under
4 Federal and applicable State law.

5 “(e) APPLICATION OF COST-SHARING TOWARDS
6 DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any
7 cost-sharing payments made pursuant to subsection (a)(2)
8 shall be counted toward any deductible or out-of-pocket
9 maximum that applies under the plan or coverage.”.

10 (2) CLERICAL AMENDMENT.—The table of con-
11 tents in section 1 of such Act is amended by insert-
12 ing after the item relating to section 727 (as in-
13 serted by section 301) the following new item:

“Sec. 728. Requirements with respect to cost-sharing for certain insulin prod-
ucts.”.

14 (c) IRC.—

15 (1) IN GENERAL.—Subchapter B of chapter
16 100 of the Internal Revenue Code of 1986, as
17 amended by sections 101 and 301, is further amend-
18 ed by adding at the end the following new section:

19 **“SEC. 9828. REQUIREMENTS WITH RESPECT TO COST-SHAR-**
20 **ING FOR CERTAIN INSULIN PRODUCTS.**

21 “(a) IN GENERAL.—For plan years beginning on or
22 after January 1, 2027, a group health plan shall provide
23 coverage of selected insulin products, and with respect to
24 such products, shall not—

1 “(1) apply any deductible; or

2 “(2) impose any cost-sharing in excess of the
3 lesser of, per 30-day supply—

4 “(A) \$35; or

5 “(B) the amount equal to 25 percent of
6 the negotiated price of the selected insulin prod-
7 uct net of all price concessions received by or on
8 behalf of the plan, including price concessions
9 received by or on behalf of third-party entities
10 providing services to the plan, such as phar-
11 macy benefit management services.

12 “(b) DEFINITIONS.—In this section:

13 “(1) SELECTED INSULIN PRODUCTS.—The term
14 ‘selected insulin products’ means at least one of each
15 dosage form (such as vial, pump, or inhaler dosage
16 forms) of each different type (such as rapid-acting,
17 short-acting, intermediate-acting, long-acting, ultra
18 long-acting, and premixed) of insulin (as defined
19 below), when available, as selected by the group
20 health plan.

21 “(2) INSULIN DEFINED.—The term ‘insulin’
22 means insulin that is licensed under subsection (a)
23 or (k) of section 351 of the Public Health Service
24 Act (42 U.S.C. 262) and continues to be marketed
25 under such section, including any insulin product

1 that has been deemed to be licensed under section
2 351(a) of such Act pursuant to section 7002(e)(4)
3 of the Biologics Price Competition and Innovation
4 Act of 2009 (Public Law 111–148) and continues to
5 be marketed pursuant to such licensure.

6 “(c) OUT-OF-NETWORK PROVIDERS.—Nothing in
7 this section requires a plan that has a network of providers
8 to provide benefits for selected insulin products described
9 in this section that are delivered by an out-of-network pro-
10 vider, or precludes a plan that has a network of providers
11 from imposing higher cost-sharing than the levels specified
12 in subsection (a) for selected insulin products described
13 in this section that are delivered by an out-of-network pro-
14 vider.

15 “(d) RULE OF CONSTRUCTION.—Subsection (a) shall
16 not be construed to require coverage of, or prevent a group
17 health plan from imposing cost-sharing other than the lev-
18 els specified in subsection (a) on, insulin products that are
19 not selected insulin products, to the extent that such cov-
20 erage is not otherwise required and such cost-sharing is
21 otherwise permitted under Federal and applicable State
22 law.

23 “(e) APPLICATION OF COST-SHARING TOWARDS
24 DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any
25 cost-sharing payments made pursuant to subsection (a)(2)

1 shall be counted toward any deductible or out-of-pocket
2 maximum that applies under the plan.”.

3 (2) CLERICAL AMENDMENT.—The table of sec-
4 tions for subchapter B of chapter 100 of the Inter-
5 nal Revenue Code of 1986, as amended by sections
6 101 and 301, is further amended by adding at the
7 end the following new item:

“Sec. 9828. Requirements with respect to cost-sharing for certain insulin prod-
ucts.”.

8 (d) NO EFFECT ON OTHER COST-SHARING.—Section
9 1302(d)(2) of the Patient Protection and Affordable Care
10 Act (42 U.S.C. 18022(d)(2)) is amended by adding at the
11 end the following new subparagraph:

12 “(D) SPECIAL RULE RELATING TO INSU-
13 LIN COVERAGE.—The exemption of coverage of
14 selected insulin products (as defined in section
15 2799A–13(b) of the Public Health Service Act)
16 from the application of any deductible pursuant
17 to section 2799A–13(a)(1) of such Act, section
18 728(a)(1) of the Employee Retirement Income
19 Security Act of 1974, or section 9828(a)(1) of
20 the Internal Revenue Code of 1986 shall not be
21 considered when determining the actuarial value
22 of a qualified health plan under this sub-
23 section.”.

1 (e) COVERAGE OF CERTAIN INSULIN PRODUCTS
2 UNDER CATASTROPHIC PLANS.—Section 1302(e) of the
3 Patient Protection and Affordable Care Act (42 U.S.C.
4 18022(e)) is amended by adding at the end the following
5 new paragraph:

6 “(4) COVERAGE OF CERTAIN INSULIN PROD-
7 UCTS.—

8 “(A) IN GENERAL.—Notwithstanding para-
9 graph (1)(B)(i), a health plan described in
10 paragraph (1) shall provide coverage of selected
11 insulin products, in accordance with section
12 2799A–13 of the Public Health Service Act, for
13 a plan year before an enrolled individual has in-
14 curred cost-sharing expenses in an amount
15 equal to the annual limitation in effect under
16 subsection (c)(1) for the plan year.

17 “(B) TERMINOLOGY.—For purposes of
18 subparagraph (A)—

19 “(i) the term ‘selected insulin prod-
20 ucts’ has the meaning given such term in
21 section 2799A–13(b) of the Public Health
22 Service Act; and

23 “(ii) the requirements of section
24 2799A–13 of such Act shall be applied by
25 deeming each reference in such section to

1 ‘individual health insurance coverage’ to be
2 a reference to a plan described in para-
3 graph (1).’.