

117TH CONGRESS
2D SESSION

S. _____

To reduce the price of insulin and provide for patient protections with respect to the cost of insulin.

IN THE SENATE OF THE UNITED STATES

_____ introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

To reduce the price of insulin and provide for patient protections with respect to the cost of insulin.

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

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) **SHORT TITLE.**—This Act may be cited as the
5 “Improving Needed Safeguards for Users of Lifesaving
6 Insulin Now Act” or the “INSULIN Act”.

7 (b) **TABLE OF CONTENTS.**—The table of contents for
8 this Act is as follows:

Sec. 1. Short title; table of contents.

TITLE I—PATIENT PROTECTIONS WITH RESPECT TO THE COST
OF INSULIN COVERED UNDER PRIVATE HEALTH INSURANCE

- Sec. 101. Certification of insulin products.
 Sec. 102. Patient protections for people with diabetes.
 Sec. 103. Requirements with respect to cost-sharing for certain insulin products.
 Sec. 104. Application to retiree and certain small group plans.
 Sec. 105. Safe harbor for absence of deductible for insulin.
 Sec. 106. Administration.

TITLE II—PATIENT PROTECTIONS WITH RESPECT TO THE COST
 OF INSULIN COVERED UNDER MEDICARE

- Sec. 201. Appropriate cost-sharing for insulin products covered under Medicare part D.
 Sec. 202. Additional protections under Medicare part D.
 Sec. 203. Administration.

1 **TITLE I—PATIENT PROTECTIONS**
 2 **WITH RESPECT TO THE COST**
 3 **OF INSULIN COVERED UNDER**
 4 **PRIVATE HEALTH INSURANCE**

5 **SEC. 101. CERTIFICATION OF INSULIN PRODUCTS.**

6 (a) IN GENERAL.—Part C of title XXVII of the Pub-
 7 lic Health Service Act (42 U.S.C. 300gg–91 et seq.) is
 8 amended—

9 (1) by redesignating the second section 2794
 10 (42 U.S.C. 300gg–95) (relating to uniform fraud
 11 and abuse referral format), as added by section
 12 6603 of the Patient Protection and Affordable Care
 13 Act (Public Law 111–148), as section 2795; and

14 (2) by adding at the end the following:

15 **“SEC. 2796. CERTIFICATION OF INSULIN PRODUCTS.**

16 “(a) IN GENERAL.—For plan years beginning on or
 17 after January 1, 2024, an insulin is certified under this
 18 section for a plan year if—

1 “(1)(A)(i) the manufacturer of such insulin
2 submits to the Secretary a request for—

3 “(I) in the case of an insulin that was li-
4 censed under section 351 and marketed on or
5 before December 31, 2021, the weighted aver-
6 age negotiated price under part D of title
7 XVIII of the Social Security Act (net of all
8 manufacturer rebates received by prescription
9 drug plans or MA-PD plans or pharmacy ben-
10 efit managers on their behalf) in plan year
11 2021 for such insulin (net of all manufacturer
12 rebates received by prescription drug plans or
13 MA-PD plans or pharmacy benefit managers on
14 their behalf); or

15 “(II) in the case of an insulin that was not
16 licensed under section 351 and marketed as of
17 December 31, 2021, the weighted average nego-
18 tiated price under part D of title XVIII of the
19 Social Security Act (net of all manufacturer re-
20 bates received by prescription drug plans or
21 MA-PD plans or pharmacy benefit managers on
22 their behalf) in plan year 2021, of, as applica-
23 ble—

24 “(aa) all rapid-acting insulin prod-
25 ucts;

1 “(bb) all short-acting insulin products;

2 “(cc) all intermediate-acting insulin

3 products;

4 “(dd) all long-acting insulin products;

5 or

6 “(ee) all pre-mixed insulin products

7 (excluding any insulin product that is

8 mixed with any non-insulin product);

9 “(ii) the Secretary responds to the request
10 under clause (i) with such price described in sub-
11 clause (I) or (II), as applicable, for such insulin for
12 the applicable plan year; and

13 “(iii) the manufacturer attests to the Secretary,
14 in a form and manner specified by the Secretary,
15 that any list price for such insulin for the applicable
16 plan year will not exceed the price provided by the
17 Secretary under clause (ii) for such plan year; or

18 “(B) it is an insulin that was certified for a
19 previous plan year under subparagraph (A), and the
20 manufacturer of such insulin submits, not later than
21 a date specified by the Secretary, an attestation that
22 the manufacturer has not increased the list price for
23 any plan year since the initial certification of such
24 insulin by more than the rate by which the consumer
25 price index for all urban consumers (all items; U.S.

1 city average) increased since the initial certification
2 under subparagraph (A), and will not increase the
3 list price during the applicable plan year for such in-
4 sulin by more than the rate by which the consumer
5 price index for all urban consumers (all items; U.S.
6 city average) increased since the initial certification;
7 and

8 “(2) the Secretary includes the insulin in the
9 list of certified insulin publicly posted under sub-
10 section (d).

11 “(b) WEIGHTED AVERAGE.—For purposes of sub-
12 section (a)(1)(A)(i), the following shall apply:

13 “(1) With respect to plan years beginning on or
14 after January 1, 2024, the weighted average nego-
15 tiated price under subclauses (I) and (II) of such
16 subsection shall be increased by the percentage in-
17 crease in the consumer price index for all urban con-
18 sumers (all items; U.S. city average) for the most
19 recent 12-month period available.

20 “(2) In calculating the weighted average nego-
21 tiated price for insulin under such subsection, the
22 Secretary shall—

23 “(A) in making such calculation under
24 subclause (II) of such subsection, consider sepa-

1 rately each insulin with the same dosage form
2 and strength; and

3 “(B) in making such calculation under
4 subclause (I) or (II) of such subsection, weight
5 the average negotiated price for, as applicable,
6 the insulin or the applicable type of insulin by
7 the number of prescriptions (for a 30-day sup-
8 ply) among enrollees in each prescription drug
9 plan and MA–PD plan under part D of title
10 XVIII of the Social Security Act for calendar
11 year 2021.

12 “(c) DECERTIFICATION.—The Secretary shall estab-
13 lish a process by which an insulin that is certified under
14 this section for a plan year is decertified for such plan
15 year if the list price for such insulin, at any point during
16 such plan year, increases above the rate that is allowable
17 under subsection (a).

18 “(d) PUBLIC POSTING.—

19 “(1) IN GENERAL.—Not later than April 15,
20 2023, and not later than January 15 of each year
21 thereafter, the Secretary shall post—

22 “(A) a list of insulins that are certified
23 under subsection (a) for the applicable plan
24 year; and

1 “(B) the weighted average negotiated price
2 under part D of title XVIII of the Social Secu-
3 rity Act, net of all manufacturer rebates re-
4 ceived by prescription drug plans or MA-PD
5 plans or pharmacy benefit managers on their
6 behalf, in plan year 2021, of, as applicable—

7 “(i) all rapid-acting insulin products;

8 “(ii) all short-acting insulin products;

9 “(iii) all intermediate-acting insulin
10 products;

11 “(iv) all long-acting insulin products;

12 or

13 “(v) all pre-mixed insulin products
14 (excluding any insulin product that is
15 mixed with any non-insulin product).

16 “(2) REVISIONS FOR DECERTIFICATION.—If the
17 Secretary decertifies an insulin under subsection (c)
18 during an applicable plan year, the Secretary shall
19 revise the list to remove such insulin.

20 “(e) AUDITS AND PENALTIES.—

21 “(1) AUDITS.—The Inspector General of the
22 Department of Health and Human Services may
23 audit the financial records and other relevant
24 records of any manufacturer submitting an attesta-
25 tion under this section.

1 “(2) PENALTIES.—

2 “(A) IN GENERAL.—The Inspector General
3 of the Department of Health and Human Serv-
4 ices shall assess against any manufacturer that
5 increases the list price of a certified insulin
6 above the price described in subclause (I) or
7 (II), as applicable, of subsection (a)(1)(A)(i)
8 and included in the attestation of such manu-
9 facturer under subsection (a)(1)(A)(iii) (re-
10 ferred to in this subparagraph as the ‘certified
11 price’), a civil penalty in the amount equal to
12 the difference between the certified price for the
13 insulin and the actual wholesale acquisition cost
14 for such insulin, multiplied by the number of
15 units sold at a price above the certified price.

16 “(B) ADMINISTRATION.—The provisions of
17 subsections (c) (with the exception of the first
18 sentence of paragraph (1) of such subsection),
19 (d), (e), (g), (h), (k), and (l) of section 1128A
20 of the Social Security Act shall apply to a civil
21 penalty under this subparagraph in the same
22 manner as such provisions apply to a penalty,
23 assessment, or proceeding under subsection (a)
24 of such section.

1 “(C) DEPOSIT.—Amounts collected under
2 subparagraph (A) shall be deposited into the
3 Federal Hospital Insurance Trust Fund under
4 section 1817 of the Social Security Act.

5 “(f) DEFINITIONS.—In this section:

6 “(1) INSULIN.—The term ‘insulin’ means insu-
7 lin that is licensed under subsection (a) or (k) of
8 section 351 and continues to be marketed pursuant
9 to such licensure.

10 “(2) LIST PRICE.—The term ‘list price’ has the
11 meaning given the term ‘wholesale acquisition cost’
12 in section 1847A(e)(6)(B) of the Social Security
13 Act.”.

14 (b) CONFORMING AMENDMENTS FOR DISCLOSURE
15 OF INFORMATION UNDER MEDICARE PART D.—

16 (1) PART D CONTRACT REQUIREMENTS.—Sec-
17 tion 1860D–12(b)(3)(D)(i) of the Social Security
18 Act (42 U.S.C. 1395w–112(b)(3)(D)(i)) is amended
19 by inserting “, or carrying out section 2796 of the
20 Public Health Service Act” after “appropriate”).

21 (2) PART D SUBSIDIES.—Section 1860D–
22 15(f)(2)(A)(i) of the Social Security Act (42 U.S.C.
23 1395w–115(f)(2)(A)(i)) is amended by inserting “or
24 section 2796 of the Public Health Service Act” after
25 “this section”.

1 **SEC. 102. PATIENT PROTECTIONS FOR PEOPLE WITH DIA-**
2 **BETES.**

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

6 **“SEC. 2799A–11. PATIENT PROTECTIONS FOR PEOPLE WITH**
7 **DIABETES.**

8 “(a) IN GENERAL.—With respect to insulin for which
9 a certification under section 2796 is in effect—

10 “(1) a group health plan or a health insurance
11 issuer offering group or individual health insurance
12 coverage shall not, and shall ensure that any entity
13 that provides pharmacy benefits management or
14 other similar services under a contract or arrange-
15 ment on behalf of such health plan or health insur-
16 ance coverage does not, directly or indirectly, receive
17 from a manufacturer of such insulin—

18 “(A) a price concession with respect to
19 such insulin received by an enrollee in the plan
20 or coverage and covered by the plan or cov-
21 erage; or

22 “(B) a price concession with respect to any
23 other product that is tied in any way to the cov-
24 erage of such insulin;

1 “(2) such insulin shall be treated as a selected
2 insulin product for purposes of section 2799A–12;
3 and

4 “(3) a group health plan, or health insurance
5 issuer with respect to such coverage, shall not im-
6 pose any prior authorization or other medical man-
7 agement requirements, or other similar conditions on
8 such insulin, except as clinically justified for safety
9 reasons, to ensure reasonable quantity limits and as
10 specified by the Secretary.

11 “(b) DEFINITIONS.—In this section:

12 “(1) INSULIN.—The term ‘insulin’ means insu-
13 lin that is licensed under subsection (a) or (k) of
14 section 351 and continues to be marketed pursuant
15 to such licensure.

16 “(2) LIST PRICE.—The term ‘list price’ has the
17 meaning given the term ‘wholesale acquisition cost’
18 in section 1847A(c)(6)(B) of the Social Security Act.

19 “(3) PRICE CONCESSION.—The term ‘price con-
20 cession’ means any discount, rebate, fee, or any
21 other direct or indirect subsidy or remuneration that
22 serves to reduce the cost of prescription drug costs
23 incurred by the group health plan or health insur-
24 ance coverage.”.

25 (b) ERISA.—

1 (1) IN GENERAL.—Subpart B of part 7 of sub-
2 title B of title I of the Employee Retirement Income
3 Security Act of 1974 (29 U.S.C. 1185 et seq.) is
4 amended by adding at the end the following:

5 **“SEC. 726. PATIENT PROTECTIONS FOR PEOPLE WITH DIA-**
6 **BETES.**

7 “(a) IN GENERAL.—With respect to insulin for which
8 a certification under section 2796 of the Public Health
9 Service Act is in effect—

10 “(1) a group health plan or a health insurance
11 issuer offering group health insurance coverage shall
12 not, and shall ensure that any entity that provides
13 pharmacy benefits management or other similar
14 services under a contract or arrangement on behalf
15 of such health plan or health insurance coverage
16 does not, directly or indirectly, receive from a manu-
17 facturer of such insulin—

18 “(A) a price concession with respect to
19 such insulin received by an enrollee in the plan
20 or coverage and covered by the plan or cov-
21 erage; or

22 “(B) a price concession with respect to any
23 other product that is tied in any way to the cov-
24 erage of such insulin;

1 “(2) such insulin shall be treated as a selected
2 insulin product for purposes of section 727; and

3 “(3) a group health plan, or health insurance
4 issuer with respect to such coverage, shall not im-
5 pose any prior authorization or medical management
6 requirements, or other similar conditions on such in-
7 sulin, except as clinically justified for safety reasons,
8 to ensure reasonable quantity limits and as specified
9 by the Secretary.

10 “(b) DEFINITIONS.—In this section:

11 “(1) INSULIN.—The term ‘insulin’ means insu-
12 lin that is licensed under subsection (a) or (k) of
13 section 351 of the Public Health Service Act (42
14 U.S.C. 262) and continues to be marketed pursuant
15 to such licensure.

16 “(2) LIST PRICE.—The term ‘list price’ has the
17 meaning given the term ‘wholesale acquisition cost’
18 in section 1847A(c)(6)(B) of the Social Security Act
19 (42 U.S.C. 1395w–3(c)(6)(B)).

20 “(3) PRICE CONCESSION.—The term ‘price con-
21 cession’ means any discount, rebate, fee, or any
22 other direct or indirect subsidy or remuneration that
23 serves to reduce the cost of prescription drug costs
24 incurred by the group health plan or health insur-
25 ance coverage.”.

1 (2) CLERICAL AMENDMENT.—The table of con-
2 tents in section 1 of the Employee Retirement In-
3 come Security Act of 1974 (29 U.S.C. 1001 et seq.)
4 is amended by inserting after the item relating to
5 section 725 the following:

“Sec. 726. Patient Protections for People with Diabetes.”.

6 (c) INTERNAL REVENUE CODE.—

7 (1) IN GENERAL.—Subchapter B of chapter
8 100 of the Internal Revenue Code of 1986 is amend-
9 ed by adding at the end the following new section:

10 **“SEC. 9826. PATIENT PROTECTIONS FOR PEOPLE WITH DIA-**
11 **BETES.**

12 “(a) IN GENERAL.—With respect to insulin for which
13 a certification under section 2796 of the Public Health
14 Service Act is in effect—

15 “(1) a group health plan shall not, and shall
16 ensure that any entity that provides pharmacy bene-
17 fits management or other similar services under a
18 contract or arrangement on behalf of such health
19 plan does not, directly or indirectly, receive from a
20 manufacturer of such insulin—

21 “(A) a price concession with respect to
22 such insulin received by an enrollee in the plan
23 and covered by the plan; or

1 “(B) a price concession with respect to any
2 other product that is tied in any way to the cov-
3 erage of such insulin;

4 “(2) such insulin shall be treated as a selected
5 insulin product for purposes of section 9827; and

6 “(3) a group health plan shall not impose any
7 prior authorization or other medical management re-
8 quirements, or other similar conditions on such insu-
9 lin, except as clinically justified for safety reasons,
10 to ensure reasonable quantity limits and as specified
11 by the Secretary.

12 “(b) DEFINITIONS.—In this section:

13 “(1) INSULIN.—The term ‘insulin’ means insu-
14 lin that is licensed under subsection (a) or (k) of
15 section 351 of the Public Health Service Act (42
16 U.S.C. 262) and continues to be marketed pursuant
17 to such licensure.

18 “(2) LIST PRICE.—The term ‘list price’ has the
19 meaning given the term ‘wholesale acquisition cost’
20 in section 1847(c)(6)(B) of the Social Security Act
21 (42 U.S.C. 1395w-3(c)(6)(B)).

22 “(3) PRICE CONCESSION.—The term ‘price con-
23 cession’ means any discount, rebate, fee, or any
24 other direct or indirect subsidy or remuneration that

1 serves to reduce the cost of prescription drug costs
2 incurred by the group health plan.”.

3 (2) CLERICAL AMENDMENT.—The table of sec-
4 tions for subchapter B of chapter 100 of such Code
5 is amended by adding at the end the following new
6 item:

“Sec. 9826. Patient Protections for People with Diabetes.”.

7 (d) APPLICATION.—The amendments made by sub-
8 sections (a), (b), and (c) shall apply beginning on January
9 1, 2024.

10 **SEC. 103. REQUIREMENTS WITH RESPECT TO COST-SHAR-**
11 **ING FOR CERTAIN INSULIN PRODUCTS.**

12 (a) IN GENERAL.—Part D of title XXVII of the Pub-
13 lic Health Service Act (42 U.S.C. 300gg–111 et seq.), as
14 amended by section 102(a), is further amended by adding
15 at the end the following:

16 **“SEC. 2799A-12. REQUIREMENTS WITH RESPECT TO COST-**
17 **SHARING FOR CERTAIN INSULIN PRODUCTS.**

18 “(a) IN GENERAL.—For plan years beginning on or
19 after January 1, 2023, a group health plan or health in-
20 surance issuer offering group or individual health insur-
21 ance coverage shall provide coverage of selected insulin
22 products, and with respect to such products, shall not—

23 “(1) apply any deductible; or

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

1 “(A) \$35; or

2 “(B) the amount equal to 25 percent of
3 the negotiated price of the selected insulin prod-
4 uct net of all price concessions received by or on
5 behalf of the plan or coverage, including price
6 concessions received by or on behalf of third-
7 party entities providing services to the plan or
8 coverage, such as pharmacy benefit manage-
9 ment services or third party administrators.

10 “(b) DEFINITIONS.—In this section:

11 “(1) SELECTED INSULIN PRODUCTS.—

12 “(A) IN GENERAL.—The term ‘selected in-
13 sulin products’—

14 “(i) means for any plan year begin-
15 ning on or after January 1, 2023, at least
16 one of each dosage form (such as vial, pen,
17 or inhaler dosage forms) of each different
18 type (such as rapid-acting, short-acting, in-
19 termediate-acting, long-acting, and pre-
20 mixed) of insulin, when such form is li-
21 censed and marketed, as selected by the
22 group health plan or health insurance
23 issuer;

1 “(ii) notwithstanding clause (i), for
2 any plan year beginning on or after Janu-
3 ary 1, 2024, includes—

4 “(I) all insulins for which a cer-
5 tification under section 2796 is in ef-
6 fect; and

7 “(II) any insulin for which a cer-
8 tification under such section 2796 was
9 in effect during the plan year, but
10 which was decertified under sub-
11 section (c) of such section during the
12 plan year, but only with respect to in-
13 dividuals who were enrolled in the
14 plan or coverage before such decerti-
15 fication.

16 “(B) CLARIFICATIONS.—

17 “(i) CERTIFIED INSULIN.—Insulin de-
18 scribed in subparagraph (A)(ii) may be
19 used to meet the requirement of subpara-
20 graph (A)(i) for the dosage form and type
21 of such insulin.

22 “(ii) PRE-MIXED INSULIN.—A pre-
23 mixed insulin product is an insulin product
24 for purposes of subparagraph (A)(i) only if

1 the product contains only insulin, and is
2 not mixed with any non-insulin product.

3 “(2) INSULIN.—The term ‘insulin’ means insu-
4 lin that is licensed under subsection (a) or (k) of
5 section 351 and continues to be marketed pursuant
6 to such licensure.

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

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

24 “(e) APPLICATION OF COST-SHARING TOWARDS
25 DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any

1 cost-sharing payments made pursuant to subsection (a)(2)
2 shall be counted toward any deductible or out-of-pocket
3 maximum that applies under the plan or coverage.”.

4 (b) NO EFFECT ON OTHER COST-SHARING.—Section
5 1302(d)(2) of the Patient Protection and Affordable Care
6 Act (42 U.S.C. 18022(d)(2)) is amended by adding at the
7 end the following new subparagraph:

8 (D) SPECIAL RULE RELATING TO INSU-
9 LIN COVERAGE.—The exemption of coverage of
10 selected insulin products (as defined in section
11 2799A–12(b) of the Public Health Service Act)
12 from the application of any deductible pursuant
13 to section 2799A–12(a)(1) of such Act, section
14 727(a)(1) of the Employee Retirement Income
15 Security Act of 1974, or section 9827(a)(1) of
16 the Internal Revenue Code of 1986 shall not be
17 considered when determining the actuarial value
18 of a qualified health plan under this sub-
19 section.”.

20 (c) COVERAGE OF CERTAIN INSULIN PRODUCTS
21 UNDER CATASTROPHIC PLANS.—Section 1302(e) of the
22 Patient Protection and Affordable Care Act (42 U.S.C.
23 18022(e)) is amended by adding at the end the following:

24 (4) COVERAGE OF CERTAIN INSULIN PROD-
25 UCTS.—

1 “(A) IN GENERAL.—Notwithstanding para-
2 graph (1)(B)(i), a health plan described in
3 paragraph (1) shall provide coverage of selected
4 insulin products, in accordance with section
5 2799A–12 of the Public Health Service Act, be-
6 fore an enrolled individual has incurred, during
7 the plan year, cost-sharing expenses in an
8 amount equal to the annual limitation in effect
9 under subsection (c)(1) for the plan year.

10 “(B) TERMINOLOGY.—For purposes of
11 subparagraph (A)—

12 “(i) the term ‘selected insulin prod-
13 ucts’ has the meaning given such term in
14 section 2799A–12(b) of the Public Health
15 Service Act; and

16 “(ii) the requirements of section
17 2799A–12 of such Act shall be applied by
18 deeming each reference in such section to
19 ‘individual health insurance coverage’ to be
20 a reference to a plan described in para-
21 graph (1).”.

22 (d) ERISA.—

23 (1) IN GENERAL.—Subpart B of part 7 of sub-
24 title B of title I of the Employee Retirement Income
25 Security Act of 1974 (29 U.S.C. 1185 et seq.), as

1 amended by section 102(b), is further amended by
2 adding at the end the following:

3 **“SEC. 727. REQUIREMENTS WITH RESPECT TO COST-SHAR-**
4 **ING FOR CERTAIN INSULIN PRODUCTS.**

5 “(a) IN GENERAL.—For plan years beginning on or
6 after January 1, 2023, a group health plan or health in-
7 surance issuer offering group health insurance coverage
8 shall provide coverage of selected insulin products, and
9 with respect to such products, shall not—

10 “(1) apply any deductible; or

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

13 “(A) \$35; or

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

22 “(b) DEFINITIONS.—In this section:

23 “(1) SELECTED INSULIN PRODUCTS.—

24 “(A) IN GENERAL.—The term ‘selected in-
25 sulin products’—

1 “(i) means for any plan year begin-
2 ning on or after January 1, 2023, at least
3 one of each dosage form (such as vial, pen,
4 or inhaler dosage forms) of each different
5 type (such as rapid-acting, short-acting, in-
6 termediate-acting, long-acting, and pre-
7 mixed) of insulin, when such form is li-
8 censed and marketed, as selected by the
9 group health plan or health insurance
10 issuer; and

11 “(ii) notwithstanding clause (i), for
12 any plan year beginning on or after Janu-
13 ary 1, 2024, includes—

14 “(I) all insulins for which a cer-
15 tification under section 2796 of the
16 Public Health Service Act is in effect;
17 and

18 “(II) any insulin for which a cer-
19 tification under such section 2796 was
20 in effect during the plan year, but
21 which was decertified under sub-
22 section (c) of such section during the
23 plan year, but only with respect to in-
24 dividuals who were enrolled in the

1 plan or coverage before such decerti-
2 fication.

3 “(B) CLARIFICATIONS.—

4 “(i) CERTIFIED INSULIN.—Insulin de-
5 scribed in subparagraph (A)(ii) may be
6 used to meet the requirement of subpara-
7 graph (A)(i) for the dosage form and type
8 of such insulin.

9 “(ii) PRE-MIXED INSULIN.—A pre-
10 mixed insulin product is an insulin product
11 for purposes of subparagraph (A)(i) only if
12 the product contains only insulin, and is
13 not mixed with any non-insulin product.

14 “(2) INSULIN.—The term ‘insulin’ means insu-
15 lin that is licensed under subsection (a) or (k) of
16 section 351 of the Public Health Service Act (42
17 U.S.C. 262) and continues to be marketed pursuant
18 to such licensure.

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

1 lin products described in this section that are delivered
2 by an out-of-network provider.

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

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

16 (2) CLERICAL AMENDMENT.—The table of con-
17 tents in section 1 of the Employee Retirement In-
18 come Security Act of 1974 (29 U.S.C. 1001 et seq.),
19 as amended by section 102(b)(2), is further amend-
20 ed by inserting after the item relating to section 726
21 the following:

“Sec. 727. Requirements with respect to cost-sharing for certain insulin prod-
ucts.”.

22 (e) INTERNAL REVENUE CODE.—

23 (1) IN GENERAL.—Subchapter B of chapter
24 100 of the Internal Revenue Code of 1986, as

1 amended by section 102(c), is further amended by
2 adding at the end the following new section:

3 **“SEC. 9827. REQUIREMENTS WITH RESPECT TO COST-SHAR-**
4 **ING FOR CERTAIN INSULIN PRODUCTS.**

5 “(a) IN GENERAL.—For plan years beginning on or
6 after January 1, 2023, a group health plan shall provide
7 coverage of selected insulin products, and with respect to
8 such products, shall not—

9 “(1) apply any deductible; or

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

12 “(A) \$35; or

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

21 “(b) DEFINITIONS.—In this section:

22 “(1) SELECTED INSULIN PRODUCTS.—

23 “(A) IN GENERAL.—The term ‘selected in-
24 sulin products’—

1 “(i) means for any plan year begin-
2 ning on or after January 1, 2023, at least
3 one of each dosage form (such as vial, pen,
4 or inhaler dosage forms) of each different
5 type (such as rapid-acting, short-acting, in-
6 termediate-acting, long-acting, and pre-
7 mixed) of insulin, when such form is li-
8 censed and marketed, as selected by the
9 group health plan; and

10 “(ii) notwithstanding clause (i), for
11 any plan year beginning on or after Janu-
12 ary 1, 2024, includes—

13 “(I) all insulins for which a cer-
14 tification under section 2796 of the
15 Public Health Service Act is in effect;
16 and

17 “(II) any insulin for which a cer-
18 tification under such section 2796 was
19 in effect during the plan year, but
20 which was decertified under sub-
21 section (c) of such section during the
22 plan year, but only with respect to in-
23 dividuals who were enrolled in the
24 plan before such decertification.

25 “(B) CLARIFICATIONS.—

1 “(i) CERTIFIED INSULIN.—Insulin de-
2 scribed in subparagraph (A)(ii) may be
3 used to meet the requirement of subpara-
4 graph (A)(i) for the dosage form and type
5 of such insulin.

6 “(ii) PRE-MIXED INSULIN.—A pre-
7 mixed insulin product is an insulin product
8 for purposes of subparagraph (A)(i) only if
9 the product contains only insulin, and is
10 not mixed with any non-insulin product.

11 “(2) INSULIN.—The term ‘insulin’ means insu-
12 lin that is licensed under subsection (a) or (k) of
13 section 351 of the Public Health Service Act (42
14 U.S.C. 262) and continues to be marketed pursuant
15 to such licensure.

16 “(c) OUT-OF-NETWORK PROVIDERS.—Nothing in
17 this section requires a plan that has a network of providers
18 to provide benefits for selected insulin products described
19 in this section that are delivered by an out-of-network pro-
20 vider, or precludes a plan that has a network of providers
21 from imposing higher cost-sharing than the levels specified
22 in subsection (a) for selected insulin products described
23 in this section that are delivered by an out-of-network pro-
24 vider.

1 “(d) **RULE OF CONSTRUCTION.**—Subsection (a) shall
2 not be construed to require coverage of, or prevent a group
3 health plan from imposing cost-sharing other than the lev-
4 els specified in subsection (a) on, insulin products that are
5 not selected insulin products, to the extent that such cov-
6 erage is not otherwise required and such cost-sharing is
7 otherwise permitted under Federal and applicable State
8 law.

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

14 (2) **CLERICAL AMENDMENT.**—The table of sec-
15 tions for subchapter B of chapter 100 of such Code,
16 as amended by section 102(c)(2), is further amended
17 by adding at the end the following new item:

“Sec. 9827. Requirements with respect to cost-sharing for certain insulin prod-
ucts.”.

18 **SEC. 104. APPLICATION TO RETIREE AND CERTAIN SMALL**
19 **GROUP PLANS.**

20 Section 732(a) of the Employee Retirement Income
21 Security Act of 1974 (29 U.S.C. 1191a(a)) is amended
22 by striking “section 711” and inserting “sections 711,
23 726, and 727”.

1 **SEC. 105. SAFE HARBOR FOR ABSENCE OF DEDUCTIBLE**
2 **FOR INSULIN.**

3 (a) IN GENERAL.—Paragraph (2) of section 223(c)
4 of the Internal Revenue Code of 1986 is amended by add-
5 ing at the end the following new subparagraph:

6 “(G) SAFE HARBOR FOR ABSENCE OF DE-
7 DUCTIBLE FOR CERTAIN INSULIN PRODUCTS.—
8 A plan shall not fail to be treated as a high de-
9 ductible health plan by reason of failing to have
10 a deductible for selected insulin products (as
11 defined in section 9827(b)).”.

12 (b) EFFECTIVE DATE.—The amendment made by
13 this section shall apply to plan years beginning after De-
14 cember 31, 2022.

15 **SEC. 106. ADMINISTRATION.**

16 (a) IMPLEMENTATION.—Notwithstanding any other
17 provision of law, the Secretary of Health and Human
18 Services, the Secretary of Labor, and the Secretary of the
19 Treasury may implement the provisions of, including the
20 amendments made by, this title for plan years 2023 and
21 2024 by program instruction or otherwise.

22 (b) NON-APPLICATION OF THE PAPERWORK REDUC-
23 TION ACT.—Chapter 35 of title 44, United States Code
24 (commonly referred to as the “Paperwork Reduction Act
25 of 1995”), shall not apply to the provisions of, including
26 the amendments made by, this title.

1 **TITLE II—PATIENT PROTEC-**
2 **TIONS WITH RESPECT TO THE**
3 **COST OF INSULIN COVERED**
4 **UNDER MEDICARE**

5 **SEC. 201. APPROPRIATE COST-SHARING FOR INSULIN**
6 **PRODUCTS COVERED UNDER MEDICARE**
7 **PART D.**

8 (a) IN GENERAL.—Section 1860D–2 of the Social
9 Security Act (42 U.S.C. 1395w–102) is amended—

10 (1) in subsection (b)—

11 (A) in paragraph (1)(A), in the matter
12 preceding clause (i), by striking “The coverage”
13 and inserting “Subject to paragraph (8), the
14 coverage”;

15 (B) in paragraph (2)—

16 (i) in subparagraph (A), in the matter
17 preceding clause (i), by striking “and (D)”
18 and inserting “and (D) and paragraph
19 (8)”;

20 (ii) in subparagraph (C)(i), in the
21 matter preceding subclause (I), by striking
22 “paragraph (4)” and inserting “para-
23 graphs (4) and (8)”;

24 (iii) in subparagraph (D)(i), in the
25 matter preceding subclause (I), by striking

1 “paragraph (4)” and inserting “para-
2 graphs (4) and (8)”;

3 (C) in paragraph (3)(A), in the matter
4 preceding clause (i), by striking “and (4)” and
5 inserting “(4), and (8)”;

6 (D) in paragraph (4)(A)(i), in the matter
7 preceding subclause (I), by striking “The cov-
8 erage” and inserting “Subject to paragraph (8),
9 the coverage”; and

10 (E) by adding at the end the following new
11 paragraph:

12 “(8) TREATMENT OF COST-SHARING FOR SE-
13 LECTED INSULIN PRODUCTS.—

14 “(A) IN GENERAL.—For plan year 2023
15 and each subsequent plan year, the following
16 rules shall apply with respect to cost-sharing for
17 a month’s supply of selected insulin products
18 (as defined in subparagraph (B)) under the
19 prescription drug plan or MA–PD plan:

20 “(i) NO APPLICATION OF DEDUCT-
21 IBLE.—The deductible under paragraph
22 (1) shall not apply with respect to such se-
23 lected insulin products.

24 “(ii) MAXIMUM COST-SHARING.—

1 insulin product under the
2 prescription drug plan or
3 MA–PD plan.

4 “(B) DEFINITIONS.—In this paragraph:

5 “(i) SELECTED INSULIN PRODUCTS.—

6 “(I) IN GENERAL.—Subject to
7 subclause (II), the term ‘selected insu-
8 lin products’—

9 “(aa) means, for any plan
10 year beginning on or after Janu-
11 ary 1, 2023, at least one of each
12 dosage form (such as vial, pen, or
13 inhaler dosage forms) of each dif-
14 ferent type (such as rapid-acting,
15 short-acting, intermediate-acting,
16 long-acting, and pre-mixed) of in-
17 sulin, when such a form is li-
18 censed and marketed, as selected
19 by the PDP sponsor offering the
20 prescription drug plan or the MA
21 organization offering the MA-PD
22 plan; and

23 “(bb) notwithstanding item
24 (aa), for any plan year beginning

1 on or after January 1, 2024, in-
2 cludes—

3 “(AA) all insulins for
4 which a certification under
5 section 2796 of the Public
6 Health Service Act is in ef-
7 fect; and

8 “(BB) any insulin for
9 which a certification under
10 such section 2796 was in ef-
11 fect during the plan year,
12 but which was decertified
13 under subsection (c) of such
14 section during the plan year,
15 but only with respect to in-
16 dividuals who were enrolled
17 in the plan before such de-
18 certification.

19 “(II) ONLY COVERED PART D
20 DRUGS.—The term ‘selected insulin
21 products’ only includes insulin that is
22 a covered part D drug (and does not
23 include insulin that is covered under
24 part B).

25 “(III) CLARIFICATIONS.—

1 “(aa) CERTIFIED INSU-
2 LIN.—Insulin described in sub-
3 clause (I)(bb) may be used to
4 meet the requirement of sub-
5 clause (I)(aa) for the dosage
6 form of such insulin.

7 “(bb) PRE-MIXED INSU-
8 LIN.—A pre-mixed insulin prod-
9 uct is an insulin product for pur-
10 poses of subclause (I)(aa) only if
11 the product contains only insulin,
12 and is not mixed with any non-
13 insulin product.

14 “(ii) INSULIN.—The term ‘insulin’
15 means insulin that is a covered part D
16 drug and is licensed under subsection (a)
17 or (k) of section 351 of the Public Health
18 Service and continues to be marketed pur-
19 suant to such licensure.”; and

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

22 “(4) TREATMENT OF COST-SHARING FOR INSU-
23 LIN PRODUCTS.—The coverage is provided in accord-
24 ance with subsection (b)(8).”.

1 (b) REQUIRED INCLUSION OF SELECTED INSULIN
2 PRODUCTS ON MEDICARE PART D FORMULARIES.—Sec-
3 tion 1860D–4(b)(3) of the Social Security Act (42 U.S.C.
4 1395w–104(b)(3)) is amended by adding at the end the
5 following new subparagraph:

6 “(I) REQUIRED INCLUSION OF SELECTED
7 INSULIN PRODUCTS.—For plan year 2023 and
8 each subsequent plan year, a PDP sponsor of-
9 fering a prescription drug plan or a Medicare
10 Advantage organization offering an MA–PD
11 plan shall include on the plan’s formulary all
12 selected insulin products (as defined in section
13 1860D–2(b)(8)(B)) for the plan.”.

14 (c) CONFORMING AMENDMENTS TO COST-SHARING
15 FOR LOW-INCOME INDIVIDUALS.—Section 1860D–14(a)
16 of the Social Security Act (42 U.S.C. 1395w–114(a)) is
17 amended—

18 (1) in paragraph (1)—

19 (A) in subparagraph (D)(iii), by adding at
20 the end the following new sentence: “For plan
21 year 2023 and each subsequent plan year, the
22 copayment amount applicable under the pre-
23 ceding sentence to a month’s supply of a se-
24 lected insulin product (as defined in section
25 1860D–2(b)(8)(B)) dispensed to the individual

1 may not exceed the applicable copayment or co-
2 insurance amount for the product under the
3 prescription drug plan or MA–PD plan in which
4 the individual is enrolled.”; and

5 (B) in subparagraph (E), by inserting the
6 following before the period at the end: “or
7 under section 1860D–2(b)(8) in the case of a
8 selected insulin product (as defined in subpara-
9 graph (B) of such section)”; and

10 (2) in paragraph (2)—

11 (A) in subparagraph (B), by striking “A
12 reduction” and inserting “Subject to section
13 1860D–2(b)(8), a reduction”;

14 (B) in subparagraph (D), by adding at the
15 end the following new sentence: “For plan year
16 2023 and each subsequent plan year, the
17 amount of the coinsurance applicable under the
18 preceding sentence to a month’s supply of a se-
19 lected insulin product (as defined in section
20 1860D–2(b)(8)(B)) dispensed to the individual
21 may not exceed the applicable copayment or co-
22 insurance amount for the product under the
23 prescription drug plan or MA–PD plan in which
24 the individual is enrolled.”; and

1 (C) in subparagraph (E), by adding at the
2 end the following new sentence: “For plan year
3 2023 and each subsequent plan year, the
4 amount of the copayment or coinsurance appli-
5 cable under the preceding sentence to a month’s
6 supply of a selected insulin product (as defined
7 in section 1860D–2(b)(8)(B)) dispensed to the
8 individual may not exceed the applicable copay-
9 ment or coinsurance amount for the product
10 under the prescription drug plan or MA–PD
11 plan in which the individual is enrolled.”.

12 **SEC. 202. ADDITIONAL PROTECTIONS UNDER MEDICARE**

13 **PART D.**

14 Section 1860D–4 of the Social Security Act (42
15 U.S.C. 1395w–104) is amended by adding at the end the
16 following new subsection:

17 “(p) **ADDITIONAL PROTECTIONS FOR ENROLLEES**
18 **WITH DIABETES.—**

19 “(1) **IN GENERAL.—**For plan year 2024 and
20 each subsequent plan year, notwithstanding any
21 other provision of this part, with respect to insulin
22 for which a certification under section 2796 of the
23 Public Health Service Act is in effect—

24 “(A) a PDP sponsor offering a prescrip-
25 tion drug plan or a Medicare Advantage organi-

1 zation offering an MA–PD plan shall not, and
2 shall ensure that any entity that provides phar-
3 macy benefits management services on behalf of
4 the prescription drug plan or MA–PD plan of-
5 fered by the sponsor or organization does not,
6 directly or indirectly, receive from a manufac-
7 turer of such insulin—

8 “(i) a price concession with respect to
9 such insulin received by an enrollee in the
10 plan; or

11 “(ii) a price concession with respect to
12 any other product that is tied in any way
13 to the coverage of such insulin; and

14 “(B) a PDP sponsor offering a prescrip-
15 tion drug plan or a Medicare Advantage organi-
16 zation offering an MA–PD plan shall not im-
17 pose any prior authorization or other utilization
18 management requirements on such insulin, ex-
19 cept as clinically justified for safety reasons, to
20 ensure reasonable quantity limits and as speci-
21 fied by the Secretary.

22 “(2) DEFINITION OF PRICE CONCESSION.—The
23 term ‘price concession’ means any discount, rebate,
24 fee, or any other direct or indirect subsidy or remu-
25 neration that serves to reduce the cost of prescrip-

1 tion drug costs incurred by the PDP sponsor offer-
2 ing the prescription drug plan or the Medicare Ad-
3 vantage organization offering the MA–PD plan.”.

4 **SEC. 203. ADMINISTRATION.**

5 (a) IMPLEMENTATION.—Notwithstanding any other
6 provision of law, the Secretary of Health and Human
7 Services may implement the provisions of, including the
8 amendments made by, this title for plan year 2023 and
9 2024 by program instruction or otherwise.

10 (b) NON-APPLICATION OF THE PAPERWORK REDUC-
11 TION ACT.—Chapter 35 of title 44, United States Code
12 (commonly referred to as the “Paperwork Reduction Act
13 of 1995”), shall not apply to the provisions of, including
14 the amendments made by, this title.

15 (c) FUNDING.—In addition to amounts otherwise
16 available, there is appropriated to the Secretary of Health
17 and Human Services, out of any money in the Treasury
18 not otherwise appropriated, \$15,000,000 for fiscal year
19 2022, to remain available until expended, to carry out the
20 provisions of, including the amendments made by, this
21 Act.