

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. Safe harbor for absence of deductible for insulin.
 Sec. 105. 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 the maximum
3 list price for such insulin during the plan year pur-
4 suant to such certification, in accordance with para-
5 graph (1) or (2) of subsection (b);

6 “(ii) the Secretary responds to the request
7 under clause (i) with a list price for such insulin for
8 the applicable plan year, in accordance with sub-
9 section (b); and

10 “(iii) the manufacturer attests to the Secretary
11 that it will not exceed the list price provided by the
12 Secretary under clause (ii) for the applicable plan
13 year; or

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

1 price index for all urban consumers (all items; U.S.
2 city average) increased since the initial certification;
3 and

4 “(2) the Secretary includes the insulin in the
5 list of certified insulin publicly posted under sub-
6 section (e).

7 “(b) LIST PRICE FOR INITIAL CERTIFICATION.—

8 “(1) IN GENERAL.—For plan years beginning
9 on or after January 1, 2024, in the case of an insu-
10 lin that was licensed under section 351 and mar-
11 keted on or before December 31, 2021, the insulin
12 may be certified under subsection (a)(1)(A) for a
13 plan year if the list price of such insulin for the ap-
14 plicable plan year is not greater than the weighted
15 average negotiated price for the same insulin under
16 part D of title XVIII of the Social Security Act net
17 of all manufacturer rebates received by prescription
18 drug plans or MA-PD plans or pharmacy benefit
19 managers on their behalf from manufacturers with
20 respect to plan year 2021.

21 “(2) SPECIAL RULE FOR CERTAIN INSULIN.—In
22 the case of an insulin that was not licensed under
23 section 351 and marketed as of December 31, 2021,
24 the manufacturer may request that such insulin be
25 initially certified under subsection (a)(1)(A) by sub-

1 mitting information attesting that the average list
2 price of such insulin for the plan year will not be
3 greater than the weighted average negotiated price
4 under part D of title XVIII of the Social Security
5 Act (net of all manufacturer rebates received by pre-
6 scription drug plans or MA-PD plans or pharmacy
7 benefit managers on their behalf) in plan year 2021,
8 of, as applicable—

9 “(A) all rapid-acting insulin products;

10 “(B) all short-acting insulin products;

11 “(C) all intermediate-acting insulin prod-
12 ucts;

13 “(D) all long-acting insulin products; or

14 “(E) all pre-mixed insulin products (ex-
15 cluding any insulin product that is mixed with
16 any non-insulin product).

17 “(c) **WEIGHTED AVERAGE.**—For purposes of sub-
18 section (b), the following shall apply:

19 “(1) The weighted average negotiated price de-
20 scribed in subsection (b)(1) shall be increased annu-
21 ally in accordance with the consumer price index for
22 all urban consumers (all items; U.S. city average).

23 “(2) In calculating the weighted average nego-
24 tiated price for insulin under paragraphs (1) and (2)
25 of subsection (b), the Secretary shall—

1 “(A) consider separately each insulin with
2 the same dosage form and strength; and

3 “(B) weight the average negotiated price
4 for such insulin by the number of enrollees in
5 each prescription drug plan and MA–PD plan
6 under part D of title XVIII of the Social Secu-
7 rity Act for the applicable year.

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

14 “(e) PUBLIC POSTING.—

15 “(1) IN GENERAL.—Not later than April 15,
16 2023, and not later than January 15 of each year
17 thereafter, the Secretary shall post—

18 “(A) a list of insulin products that are cer-
19 tified under subsection (a) for the applicable
20 plan year; and

21 “(B) the weighted average negotiated price
22 under part D of title XVIII of the Social Secu-
23 rity Act, net of all manufacturer rebates re-
24 ceived by prescription drug plans or MA-PD
25 plans or pharmacy benefit managers on their

1 behalf, in plan year 2021, of, as applicable,
2 with respect to certified insulins—

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

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

5 “(iii) all intermediate-acting insulin
6 products;

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

8 or

9 “(v) all pre-mixed insulin products
10 (excluding any insulin product that is
11 mixed with any non-insulin product).

12 “(2) REVISIONS FOR DECERTIFICATION.—In
13 the case the Secretary decertifies an insulin under
14 subsection (d) during an applicable plan year, the
15 Secretary shall revise the list to remove such insulin.

16 “(f) AUDITS AND PENALTIES.—

17 “(1) AUDITS.—The Inspector General of the
18 Department of Health and Human Services may
19 audit the financial records and other relevant
20 records of any manufacturer submitting data under
21 this section.

22 “(2) PENALTIES.—

23 “(A) IN GENERAL.—The Inspector General
24 of the Department of Health and Human Serv-
25 ices shall assess against any manufacturer that

1 increases the list price of a certified insulin
2 above the maximum list price that applies
3 under subsection (a)(1) pursuant to the certifi-
4 cation, a civil penalty in the amount equal to
5 the difference between such maximum list price
6 for the insulin and the actual wholesale acquisi-
7 tion cost for such insulin, multiplied by the
8 number of units sold at a price above such max-
9 imum list price.

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

19 “(C) DEPOSIT.—Amounts collected under
20 subparagraph (A) shall be deposited into the
21 Federal Hospital Insurance Trust Fund under
22 section 1817 of the Social Security Act.

23 “(g) DEFINITIONS.—In this section:

24 “(1) INSULIN.—The term ‘insulin’ means insu-
25 lin that is licensed under subsection (a) or (k) of

1 section 351 and continues to be marketed pursuant
2 to such licensure.

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

7 (b) CONFORMING AMENDMENTS FOR DISCLOSURE
8 OF INFORMATION.—(1) Section 1927(b)(3)(D) of the So-
9 cial Security Act (42 U.S.C. 1396r-8(b)(3)(D)) is amend-
10 ed—

11 (A) in clause (iv), by striking “and” at the end;

12 (B) in clause (v), by striking the period at the
13 end and inserting “; and”; and

14 (C) by inserting after clause (v) the following
15 new clause:

16 “(i) as the Secretary determines nec-
17 essary to carry out section 2796 of the
18 Public Health Service Act.”.

19 (2) Section 1860D-12(b)(3)(D)(i) of the Social Secu-
20 rity Act (42 U.S.C. 1395w-112(b)(3)(D)(i)) is amended
21 by inserting “, or carrying out section 2796 of the Public
22 Health Service Act” before the period at the end.

23 (3) Section 1860D-15(d)(2)(B) of the Social Secu-
24 rity Act (42 U.S.C. 1395w-115(d)(2)(B)) is amended by

1 inserting “or section 2796 of the Public Health Service
2 Act” before the period at the end.

3 (4) Section 1860D–15(f)(2)(A)(i) of the Social Secu-
4 rity Act (42 U.S.C. 1395w–115(f)(2)(A)(i)) is amended
5 by inserting “or section 2796 of the Public Health Service
6 Act” after “this section”.

7 **SEC. 102. PATIENT PROTECTIONS FOR PEOPLE WITH DIA-**
8 **BETES.**

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

12 **“SEC. 2799A–11. PATIENT PROTECTIONS FOR PEOPLE WITH**
13 **DIABETES.**

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

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

24 “(A) a price concession with respect to
25 such insulin received by an enrollee in the plan

1 or coverage and covered by the plan or cov-
2 erage; or

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

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

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

16 “(b) DEFINITIONS.—In this section:

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

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

24 “(3) PRICE CONCESSION.—The term ‘price con-
25 cession’ means any discount, rebate, fee, or any

1 other direct or indirect subsidy or remuneration that
2 serves to reduce the cost of prescription drug costs
3 incurred by the group health plan or health insur-
4 ance coverage.”.

5 (b) ERISA.—

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

10 **“SEC. 726. 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 or a health insurance
16 issuer offering group health insurance coverage shall
17 not, and shall ensure that any entity that provides
18 pharmacy benefits management or other similar
19 services under a contract or arrangement on behalf
20 of such health plan or health insurance coverage
21 does not, directly or indirectly, receive from a manu-
22 facturer of such insulin—

23 “(A) a price concession with respect to
24 such insulin received by an enrollee in the plan

1 or coverage and covered by the plan or cov-
2 erage; or

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

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

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

15 “(b) DEFINITIONS.—In this section:

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

21 “(2) LIST PRICE.—The term ‘list price’ has the
22 meaning given the term ‘wholesale acquisition cost’
23 in section 1847A(c)(6)(B) of the Social Security Act
24 (42 U.S.C. 1395w–3(c)(6)(B)).

1 plan does not, directly or indirectly, receive from a
2 manufacturer of such insulin—

3 “(A) a price concession with respect to
4 such insulin received by an enrollee in the plan
5 and covered by the plan; or

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

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

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

17 “(b) DEFINITIONS.—In this section:

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

23 “(2) LIST PRICE.—The term ‘list price’ has the
24 meaning given the term ‘wholesale acquisition cost’

1 in section 1847(c)(6)(B) of the Social Security Act
2 (42 U.S.C. 1395w-3(e)(6)(B)).

3 “(3) PRICE CONCESSION.—The term ‘price con-
4 cession’ means any discount, rebate, fee, or any
5 other direct or indirect subsidy or remuneration that
6 serves to reduce the cost of prescription drug costs
7 incurred by the group health plan.”.

8 (2) CLERICAL AMENDMENT.—The table of sec-
9 tions for subchapter B of chapter 100 of such Code
10 is amended by adding at the end the following new
11 item:

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

12 (d) APPLICATION.—The amendments made by sub-
13 sections (a), (b), and (c) shall apply beginning on January
14 1, 2024.

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

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

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

23 “(a) IN GENERAL.—For plan years beginning on or
24 after January 1, 2023, a group health plan or health in-
25 surance issuer offering group or individual health insur-

1 ance coverage shall provide coverage of selected insulin
2 products, and with respect to such products, shall not—

3 “(1) apply any deductible; or

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

6 “(A) \$35; or

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

15 “(b) DEFINITIONS.—In this section:

16 “(1) SELECTED INSULIN PRODUCTS.—

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

19 “(i) means for any plan year begin-
20 ning on or after January 1, 2023, at least
21 one of each dosage form (such as vial, pen,
22 or inhaler dosage forms) of each different
23 type (such as rapid-acting, short-acting, in-
24 termediate-acting, long-acting, and pre-
25 mixed) of insulin, when such form is li-

1 censed and marketed, as selected by the
2 group health plan or health insurance
3 issuer;

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

7 “(I) all insulins for which a cer-
8 tification under section 2796 is in ef-
9 fect; and

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

19 “(B) CLARIFICATIONS.—

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

1 “(ii) PRE-MIXED INSULIN.—A pre-
2 mixed insulin product is an insulin product
3 for purposes of subparagraph (A)(i) only if
4 the product contains only insulin, and is
5 not mixed with any non-insulin product.

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

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

1 quired and such cost-sharing is otherwise permitted under
2 Federal and applicable State law.

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

8 (b) 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–12(b) of the Public Health Service Act)
16 from the application of any deductible pursuant
17 to section 2799A–12(a)(1) of such Act, section
18 727(a)(1) of the Employee Retirement Income
19 Security Act of 1974, or section 9827(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.”.

24 (c) COVERAGE OF CERTAIN INSULIN PRODUCTS
25 UNDER CATASTROPHIC PLANS.—Section 1302(e) of the

1 Patient Protection and Affordable Care Act (42 U.S.C.
2 18022(e)) is amended by adding at the end the following:

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

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

14 “(B) TERMINOLOGY.—For purposes of
15 subparagraph (A)—

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

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

1 (d) ERISA.—

2 (1) IN GENERAL.—Subpart B of part 7 of sub-
3 title B of title I of the Employee Retirement Income
4 Security Act of 1974 (29 U.S.C. 1185 et seq.), as
5 amended by section 102(b), is further amended by
6 adding at the end the following:

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

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

14 “(1) apply any deductible; or

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

17 “(A) \$35; or

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

1 “(b) DEFINITIONS.—In this section:

2 “(1) SELECTED INSULIN PRODUCTS.—

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

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

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

18 “(I) all insulins for which a cer-
19 tification under section 2796 of the
20 Public Health Service Act is in effect;
21 and

22 “(II) any insulin for which a cer-
23 tification under such section 2796 was
24 in effect during the plan year, but
25 which was decertified under sub-

1 section (e) of such section during the
2 plan year, but only with respect to in-
3 dividuals who were enrolled in the
4 plan or coverage before such decerti-
5 fication.

6 “(B) CLARIFICATIONS.—

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

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

17 “(2) INSULIN.—The term ‘insulin’ means insu-
18 lin that is licensed under subsection (a) or (k) of
19 section 351 of the Public Health Service Act (42
20 U.S.C. 262) and continues to be marketed pursuant
21 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 (2) **CLERICAL AMENDMENT.**—The table of con-
20 tents in section 1 of the Employee Retirement In-
21 come Security Act of 1974 (29 U.S.C. 1001 et seq.),
22 as amended by section 102(b)(2), is further amend-
23 ed by inserting after the item relating to section 726
24 the following:

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

1 (e) INTERNAL REVENUE CODE.—

2 (1) IN GENERAL.—Subchapter B of chapter
3 100 of the Internal Revenue Code of 1986, as
4 amended by section 102(c), is further amended by
5 adding at the end the following new section:

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

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

12 “(1) apply any deductible; or

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

15 “(A) \$35; or

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

24 “(b) DEFINITIONS.—In this section:

25 “(1) SELECTED INSULIN PRODUCTS.—

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

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

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

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

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

1 dividuals who were enrolled in the
2 plan before such decertification.

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 that has a network of providers
21 to provide benefits for selected insulin products described
22 in this section that are delivered by an out-of-network pro-
23 vider, or precludes a plan that has a network of providers
24 from imposing higher cost-sharing than the levels specified
25 in subsection (a) for selected insulin products described

1 in this section that are delivered by an out-of-network pro-
2 vider.

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

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

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

20 **SEC. 104. SAFE HARBOR FOR ABSENCE OF DEDUCTIBLE**
21 **FOR INSULIN.**

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

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

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

10 **SEC. 105. ADMINISTRATION.**

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

17 (b) NON-APPLICATION OF THE PAPERWORK REDUC-
18 TION ACT.—Chapter 35 of title 44, United States Code
19 (commonly referred to as the “Paperwork Reduction Act
20 of 1995”), shall not apply to the provisions of, including
21 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 “(I) IN GENERAL.—The coverage
2 shall provide benefits for such selected
3 insulin products, regardless of wheth-
4 er an individual has reached the ini-
5 tial coverage limit under paragraph
6 (3) or the annual out-of-pocket
7 threshold under paragraph (4), with
8 cost-sharing for a month’s supply that
9 does not exceed the maximum cost-
10 sharing amount (as defined in sub-
11 clause (II)).

12 “(II) MAXIMUM COST-SHARING
13 AMOUNT.—For purposes of subclause
14 (I), the term ‘maximum cost-sharing
15 amount’ means, with respect to such
16 selected insulin products dispensed—

17 “(aa) during plan year
18 2023, \$35; and

19 “(bb) during plan year 2024
20 or subsequent plan year, the less-
21 er of—

22 “(AA) \$35; or

23 “(BB) an amount equal
24 to 25 percent of the nego-
25 tiated price of the selected

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.—The term ‘se-
7 lected insulin products’—

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

22 “(bb) notwithstanding item
23 (aa), for any plan year beginning
24 on or after January 1, 2024, in-
25 cludes—

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

6 “(BB) any insulin for
7 which a certification under
8 such section 2796 was in ef-
9 fect during the plan year,
10 but which was decertified
11 under subsection (e) of such
12 section during the plan year,
13 but only with respect to in-
14 dividuals who were enrolled
15 in the plan or coverage be-
16 fore such decertification.

17 “(II) ONLY COVERED PART D
18 DRUGS.—The term ‘selected insulin
19 products’ only includes insulin that is
20 a covered part D drug (and does on
21 include insulin that is covered under
22 part B).

23 “(III) CLARIFICATIONS.—

24 “(aa) CERTIFIED INSU-
25 LIN.—Insulin described in sub-

1 clause (I)(bb) may be used to
2 meet the requirement of sub-
3 clause (I)(aa) for the dosage
4 form of such insulin.

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

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

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

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

23 (b) REQUIRED INCLUSION OF SELECTED INSULIN
24 PRODUCTS ON MEDICARE PART D FORMULARIES.—Sec-
25 tion 1860D–4(b)(3) of the Social Security Act (42 U.S.C.

1 1395w–104(b)(3)) is amended by adding at the end the
2 following new subparagraph:

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

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

15 (1) in paragraph (1)—

16 (A) in subparagraph (D)(iii), by adding at
17 the end the following new sentence: “For plan
18 year 2023 and each subsequent plan year, the
19 copayment amount applicable under the pre-
20 ceeding sentence to a month’s supply of a se-
21 lected insulin product (as defined in section
22 1860D–2(b)(8)(B)) dispensed to the individual
23 may not exceed the applicable copayment or co-
24 insurance amount for the product under the

1 prescription drug plan or MA–PD plan in which
2 the individual is enrolled.”; and

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

8 (2) in paragraph (2)—

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

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

23 (C) in subparagraph (E), by adding at the
24 end the following new sentence: “For plan year
25 2023 and each subsequent plan year, the

1 amount of the copayment or coinsurance appli-
2 cable under the preceding sentence to a month’s
3 supply of a selected insulin product (as defined
4 in section 1860D–2(b)(8)(B)) dispensed to the
5 individual may not exceed the applicable copy-
6 ment or coinsurance amount for the product
7 under the prescription drug plan or MA–PD
8 plan in which the individual is enrolled.”.

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

10 **PART D.**

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

14 “(p) **ADDITIONAL PROTECTIONS FOR ENROLLEES**
15 **WITH DIABETES.—**

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

21 “(A) a PDP sponsor offering a prescrip-
22 tion drug plan or a Medicare Advantage organi-
23 zation offering an MA–PD plan shall not, and
24 shall ensure that any entity that provides phar-
25 macy benefits management services on behalf of

1 the prescription drug plan or MA–PD plan of-
2 fered by the sponsor or organization does not,
3 directly or indirectly, receive from a manufac-
4 turer of such insulin—

5 “(i) a price concession with respect to
6 such insulin received by an enrollee in the
7 plan; or

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

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

19 “(2) DEFINITION OF PRICE CONCESSION.—The
20 term ‘price concession’ means any discount, rebate,
21 fee, or any other direct or indirect subsidy or remu-
22 neration that serves to reduce the cost of prescrip-
23 tion drug costs incurred by the PDP sponsor offer-
24 ing the prescription drug plan or the Medicare Ad-
25 vantage organization offering the MA–PD plan.”.

1 **SEC. 203. ADMINISTRATION.**

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

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

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