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.

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

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

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

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

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 WITH RESPECT TO THE COST OF INSULIN COVERED UNDER PRIVATE HEALTH INSURANCE

SEC. 101. CERTIFICATION OF INSULIN PRODUCTS.

(a) In General.—Part C of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–91 et seq.) is amended—

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

(2) by adding at the end the following:

“SEC. 2796. CERTIFICATION OF INSULIN PRODUCTS.

“(a) In General.—For plan years beginning on or after January 1, 2024, an insulin is certified under this section for a plan year if—
“(1)(A)(i) the manufacturer of such insulin submits to the Secretary a request for—

“(I) in the case of an insulin that was licensed under section 351 and marketed on or before December 31, 2021, the weighted average negotiated price under part D of title XVIII of the Social Security Act (net of all manufacturer rebates received by prescription drug plans or MA-PD plans or pharmacy benefit managers on their behalf) in plan year 2021 for such insulin (net of all manufacturer rebates received by prescription drug plans or MA-PD plans or pharmacy benefit managers on their behalf); or

“(II) in the case of an insulin that was not licensed under section 351 and marketed as of December 31, 2021, the weighted average negotiated price under part D of title XVIII of the Social Security Act (net of all manufacturer rebates received by prescription drug plans or MA-PD plans or pharmacy benefit managers on their behalf) in plan year 2021, of, as applicable—

“(aa) all rapid-acting insulin products;
“(bb) all short-acting insulin products;

“(cc) all intermediate-acting insulin products;

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

“(ee) all pre-mixed insulin products (excluding any insulin product that is mixed with any non-insulin product);

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

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

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

city average) increased since the initial certification;
and

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

“(b) **Weighted Average.**—For purposes of sub-
section (a)(1)(A)(i), the following shall apply:

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

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

“(A) in making such calculation under
subclause (II) of such subsection, consider sepa-
rately each insulin with the same dosage form
and strength; and

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

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

“(d) PUBLIC POSTING.—

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

“(A) a list of insulins that are certified
under subsection (a) for the applicable plan
year; and
“(B) the weighted average negotiated price under part D of title XVIII of the Social Security Act, net of all manufacturer rebates received by prescription drug plans or MA-PD plans or pharmacy benefit managers on their behalf, in plan year 2021, of, as applicable—

“(i) all rapid-acting insulin products;
“(ii) all short-acting insulin products;
“(iii) all intermediate-acting insulin products;
“(iv) all long-acting insulin products;

or

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

“(2) Revisions for Decertification.—If the Secretary decertifies an insulin under subsection (c) during an applicable plan year, the Secretary shall revise the list to remove such insulin.

“(e) Audits and Penalties.—

“(1) Audits.—The Inspector General of the Department of Health and Human Services may audit the financial records and other relevant records of any manufacturer submitting an attestation under this section.
“(2) Penalties.—

“(A) In General.—The Inspector General of the Department of Health and Human Services shall assess against any manufacturer that increases the list price of a certified insulin above the price described in subclause (I) or (II), as applicable, of subsection (a)(1)(A)(i) and included in the attestation of such manufacturer under subsection (a)(1)(A)(iii) (referred to in this subparagraph as the ‘certified price’), a civil penalty in the amount equal to the difference between the certified price for the insulin and the actual wholesale acquisition cost for such insulin, multiplied by the number of units sold at a price above the certified price.

“(B) Administration.—The provisions of subsections (c) (with the exception of the first sentence of paragraph (1) of such subsection), (d), (e), (g), (h), (k), and (l) of section 1128A of the Social Security Act shall apply to a civil penalty under this subparagraph in the same manner as such provisions apply to a penalty, assessment, or proceeding under subsection (a) of such section.
“(C) DEPOSIT.—Amounts collected under
subparagraph (A) shall be deposited into the
Federal Hospital Insurance Trust Fund under
section 1817 of the Social Security Act.

“(f) DEFINITIONS.—In this section:

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

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

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

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

(2) PART D SUBSIDIES.—Section 1860D–
1395w–115(f)(2)(A)(i)) is amended by inserting “or
section 2796 of the Public Health Service Act” after
“this section”.

SEC. 102. PATIENT PROTECTIONS FOR PEOPLE WITH DIABETES.

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

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

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

“(1) a group health plan or a health insurance issuer offering group or individual health insurance coverage shall not, and shall ensure that any entity that provides pharmacy benefits management or other similar services under a contract or arrangement on behalf of such health plan or health insurance coverage does not, directly or indirectly, receive from a manufacturer of such insulin—

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

“(B) a price concession with respect to any other product that is tied in any way to the coverage of such insulin;
“(2) such insulin shall be treated as a selected insulin product for purposes of section 2799A–12; and

“(3) a group health plan, or health insurance issuer with respect to such coverage, shall not impose any prior authorization or other medical management requirements, or other similar conditions on such insulin, except as clinically justified for safety reasons, to ensure reasonable quantity limits and as specified by the Secretary.

“(b) DEFINITIONS.—In this section:

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

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

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

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

"SEC. 726. PATIENT PROTECTIONS FOR PEOPLE WITH DIABETES.

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

"(1) a group health plan or a health insurance issuer offering group health insurance coverage shall not, and shall ensure that any entity that provides pharmacy benefits management or other similar services under a contract or arrangement on behalf of such health plan or health insurance coverage does not, directly or indirectly, receive from a manufacturer of such insulin—

"(A) a price concession with respect to such insulin received by an enrollee in the plan or coverage and covered by the plan or coverage; or

"(B) a price concession with respect to any other product that is tied in any way to the coverage of such insulin;"
“(2) such insulin shall be treated as a selected insulin product for purposes of section 727; and

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

“(b) DEFINITIONS.—In this section:

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

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

“(3) PRICE CONCESSION.—The term ‘price con-
cession’ means any discount, rebate, fee, or any other direct or indirect subsidy or remuneration that serves to reduce the cost of prescription drug costs incurred by the group health plan or health insur-
ance coverage.”.
(2) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.) is amended by inserting after the item relating to section 725 the following:

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

(c) INTERNAL REVENUE CODE.—

(1) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

“SEC. 9826. PATIENT PROTECTIONS FOR PEOPLE WITH DIABETES.

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

“(1) a group health plan shall not, and shall ensure that any entity that provides pharmacy benefits management or other similar services under a contract or arrangement on behalf of such health plan does not, directly or indirectly, receive from a manufacturer of such insulin—

“(A) a price concession with respect to such insulin received by an enrollee in the plan and covered by the plan; or
“(B) a price concession with respect to any other product that is tied in any way to the coverage of such insulin;

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

“(3) a group health plan shall not impose any prior authorization or other medical management requirements, or other similar conditions on such insulin, except as clinically justified for safety reasons, to ensure reasonable quantity limits and as specified by the Secretary.

“(b) DEFINITIONS.—In this section:

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

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

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

(2) CLERICAL AMENDMENT.—The table of sections for subchapter B of chapter 100 of such Code is amended by adding at the end the following new item:

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

(d) APPLICATION.—The amendments made by subsections (a), (b), and (c) shall apply beginning on January 1, 2024.

SEC. 103. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

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

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

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

“(1) apply any deductible; or

“(2) impose any cost-sharing requirements in excess of the lesser of, per 30-day supply—
“(A) $35; or

“(B) the amount equal to 25 percent of the negotiated price of the selected insulin product net of all price concessions received by or on behalf of the plan or coverage, including price concessions received by or on behalf of third-party entities providing services to the plan or coverage, such as pharmacy benefit management services or third party administrators.

“(b) DEFINITIONS.—In this section:

“(1) SELECTED INSULIN PRODUCTS.—

“(A) IN GENERAL.—The term ‘selected insulin products’—

“(i) means for any plan year beginning on or after January 1, 2023, at least one of each dosage form (such as vial, pen, or inhaler dosage forms) of each different type (such as rapid-acting, short-acting, intermediate-acting, long-acting, and pre-mixed) of insulin, when such form is licensed and marketed, as selected by the group health plan or health insurance issuer;
“(ii) notwithstanding clause (i), for any plan year beginning on or after January 1, 2024, includes—

“(I) all insulins for which a certification under section 2796 is in effect; and

“(II) any insulin for which a certification under such section 2796 was in effect during the plan year, but which was decertified under subsection (c) of such section during the plan year, but only with respect to individuals who were enrolled in the plan or coverage before such decertification.

“(B) CLARIFICATIONS.—

“(i) CERTIFIED INSULIN.—Insulin described in subparagraph (A)(ii) may be used to meet the requirement of subparagraph (A)(i) for the dosage form and type of such insulin.

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

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

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

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

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

(b) No Effect on Other Cost-sharing.—Section 1302(d)(2) of the Patient Protection and Affordable Care Act (42 U.S.C. 18022(d)(2)) is amended by adding at the end the following new subparagraph:

“(D) Special rule relating to insulin coverage.—The exemption of coverage of selected insulin products (as defined in section 2799A–12(b) of the Public Health Service Act) from the application of any deductible pursuant to section 2799A–12(a)(1) of such Act, section 727(a)(1) of the Employee Retirement Income Security Act of 1974, or section 9827(a)(1) of the Internal Revenue Code of 1986 shall not be considered when determining the actuarial value of a qualified health plan under this subsection.”.

(c) Coverage of Certain Insulin Products Under Catastrophic Plans.—Section 1302(e) of the Patient Protection and Affordable Care Act (42 U.S.C. 18022(e)) is amended by adding at the end the following:

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

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

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

“(ii) the requirements of section 2799A–12 of such Act shall be applied by deeming each reference in such section to ‘individual health insurance coverage’ to be a reference to a plan described in paragraph (1).”.

(d) ERISA.—

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

“SEC. 727. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

“(a) In General.—For plan years beginning on or after January 1, 2023, a group health plan or health insurance issuer offering group health insurance coverage shall provide coverage of selected insulin products, and with respect to such products, shall not—

“(1) apply any deductible; or

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

“(A) $35; or

“(B) the amount equal to 25 percent of the negotiated price of the selected insulin product net of all price concessions received by or on behalf of the plan or coverage, including price concessions received by or on behalf of third-party entities providing services to the plan or coverage, such as pharmacy benefit management services or third party administrators.

“(b) Definitions.—In this section:

“(1) Selected insulin products.—

“(A) In general.—The term ‘selected insulin products’—
“(i) means for any plan year beginning on or after January 1, 2023, at least one of each dosage form (such as vial, pen, or inhaler dosage forms) of each different type (such as rapid-acting, short-acting, intermediate-acting, long-acting, and premixed) of insulin, when such form is licensed and marketed, as selected by the group health plan or health insurance issuer; and

“(ii) notwithstanding clause (i), for any plan year beginning on or after January 1, 2024, includes—

“(I) all insulins for which a certification under section 2796 of the Public Health Service Act is in effect; and

“(II) any insulin for which a certification under such section 2796 was in effect during the plan year, but which was decertified under subsection (c) of such section during the plan year, but only with respect to individuals who were enrolled in the
plan or coverage before such decertification.

“(B) CLARIFICATIONS.—

“(i) CERTIFIED INSULIN.—Insulin described in subparagraph (A)(ii) may be used to meet the requirement of subparagraph (A)(i) for the dosage form and type of such insulin.

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

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

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

"(d) Rule of Construction.—Subsection (a) shall
not be construed to require coverage of, or prevent a group
health plan or health insurance coverage from imposing
cost-sharing other than the levels specified in subsection
(a) on, insulin products that are not selected insulin prod-
ucts, to the extent that such coverage is not otherwise re-
quired and such cost-sharing is otherwise permitted under
Federal and applicable State law.

"(e) Application of Cost-Sharing Towards
Deductibles and Out-of-Pocket Maximums.—Any
cost-sharing payments made pursuant to subsection (a)(2)
shall be counted toward any deductible or out-of-pocket
maximum that applies under the plan or coverage.”.

(2) Clerical Amendment.—The table of con-
tents in section 1 of the Employee Retirement In-
as amended by section 102(b)(2), is further amend-
ed by inserting after the item relating to section 726
the following:

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

(e) Internal Revenue Code.—

(1) In General.—Subchapter B of chapter
100 of the Internal Revenue Code of 1986, as
amended by section 102(c), is further amended by adding at the end the following new section:

"SEC. 9827. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

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

“(1) apply any deductible; or

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

“(A) $35; or

“(B) the amount equal to 25 percent of the negotiated price of the selected insulin product net of all price concessions received by or on behalf of the plan, including price concessions received by or on behalf of third-party entities providing services to the plan, such as pharmacy benefit management services or third party administrators.

“(b) Definitions.—In this section:

“(1) Selected insulin products.—

“(A) In general.—The term ‘selected insulin products’—
“(i) means for any plan year beginning on or after January 1, 2023, at least one of each dosage form (such as vial, pen, or inhaler dosage forms) of each different type (such as rapid-acting, short-acting, intermediate-acting, long-acting, and premixed) of insulin, when such form is licensed and marketed, as selected by the group health plan; and

“(ii) notwithstanding clause (i), for any plan year beginning on or after January 1, 2024, includes—

“(I) all insulins for which a certification under section 2796 of the Public Health Service Act is in effect; and

“(II) any insulin for which a certification under such section 2796 was in effect during the plan year, but which was decertified under subsection (c) of such section during the plan year, but only with respect to individuals who were enrolled in the plan before such decertification.

“(B) CLARIFICATIONS.—
“(i) CERTIFIED INSULIN.—Insulin described in subparagraph (A)(ii) may be used to meet the requirement of subparagraph (A)(i) for the dosage form and type of such insulin.

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

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

“(e) OUT-OF-NETWORK PROVIDERS.—Nothing in this section requires a plan that has a network of providers to provide benefits for selected insulin products described in this section that are delivered by an out-of-network provider, or precludes a plan that has a network of providers from imposing higher cost-sharing than the levels specified in subsection (a) for selected insulin products described in this section that are delivered by an out-of-network provider.
“(d) RULE OF CONSTRUCTION.—Subsection (a) shall not be construed to require coverage of, or prevent a group health plan from imposing cost-sharing other than the levels specified in subsection (a) on, insulin products that are not selected insulin products, to the extent that such coverage is not otherwise required and such cost-sharing is otherwise permitted under Federal and applicable State law.

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

(2) CLERICAL AMENDMENT.—The table of sections for subchapter B of chapter 100 of such Code, as amended by section 102(c)(2), is further amended by adding at the end the following new item:

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

SEC. 104. APPLICATION TO RETIREE AND CERTAIN SMALL GROUP PLANS.

Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191a(a)) is amended by striking “section 711” and inserting “sections 711, 726, and 727”.
SEC. 105. SAFE HARBOR FOR ABSENCE OF DEDUCTIBLE FOR INSULIN.

(a) In General.—Paragraph (2) of section 223(c) of the Internal Revenue Code of 1986 is amended by adding at the end the following new subparagraph:

“(G) Safe harbor for absence of deductible for certain insulin products.—A plan shall not fail to be treated as a high deductible health plan by reason of failing to have a deductible for selected insulin products (as defined in section 9827(b)).”.

(b) Effective Date.—The amendment made by this section shall apply to plan years beginning after December 31, 2022.

SEC. 106. ADMINISTRATION.

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

(b) Non-application of the Paperwork Reduction Act.—Chapter 35 of title 44, United States Code (commonly referred to as the “Paperwork Reduction Act of 1995”), shall not apply to the provisions of, including the amendments made by, this title.
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.

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

(1) in subsection (b)—

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

(B) in paragraph (2)—

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

(ii) in subparagraph (C)(i), in the matter preceding subclause (I), by striking “paragraph (4)” and inserting “paragraphs (4) and (8)”;

and

(iii) in subparagraph (D)(i), in the matter preceding subclause (I), by striking
“paragraph (4)” and inserting “paragraphs (4) and (8)”;

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

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

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

“(8) TREATMENT OF COST-SHARING FOR SELECTED INSULIN PRODUCTS.—

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

“(i) NO APPLICATION OF DEDUCTIBLE.—The deductible under paragraph (1) shall not apply with respect to such selected insulin products.

“(ii) MAXIMUM COST-SHARING.—
“(I) IN GENERAL.—The coverage shall provide benefits for such selected insulin products, regardless of whether an individual has reached the initial coverage limit under paragraph (3) or the annual out-of-pocket threshold under paragraph (4), with cost-sharing for a month’s supply that does not exceed the maximum cost-sharing amount (as defined in subclause (II)).

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

“(aa) during plan year 2023, $35; and

“(bb) during plan year 2024 or subsequent plan year, the lesser of—

“(AA) $35; or

“(BB) an amount equal to 25 percent of the negotiated price of the selected
insulin product under the
prescription drug plan or
MA–PD plan.

“(B) DEFINITIONS.—In this paragraph:

“(i) SELECTED INSULIN PRODUCTS.—

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

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

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

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

“(BB) any insulin for
which a certification under
such section 2796 was in ef-
flect during the plan year,
but which was decertified
under subsection (e) of such
section during the plan year,
but only with respect to in-
dividuals who were enrolled
in the plan before such de-
certification.

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

“(III) CLARIFICATIONS.—
“(aa) CERTIFIED INSULIN.—Insulin described in subclause (I)(bb) may be used to meet the requirement of subclause (I)(aa) for the dosage form of such insulin.

“(bb) PRE-MIXED INSULIN.—A pre-mixed insulin product is an insulin product for purposes of subclause (I)(aa) only if the product contains only insulin, and is not mixed with any non-insulin product.

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

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

“(4) TREATMENT OF COST-SHARING FOR INSULIN PRODUCTS.—The coverage is provided in accordance with subsection (b)(8).”.
(b) Required Inclusion of Selected Insulin Products on Medicare Part D Formularies.—Section 1860D–4(b)(3) of the Social Security Act (42 U.S.C. 1395w–104(b)(3)) is amended by adding at the end the following new subparagraph:

"(I) Required inclusion of selected insulin products.—For plan year 2023 and each subsequent plan year, a PDP sponsor offering a prescription drug plan or a Medicare Advantage organization offering an MA–PD plan shall include on the plan's formulary all selected insulin products (as defined in section 1860D–2(b)(8)(B)) for the plan."

(c) Conforming Amendments to Cost-sharing for Low-income Individuals.—Section 1860D–14(a) of the Social Security Act (42 U.S.C. 1395w–114(a)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (D)(iii), by adding at the end the following new sentence: "For plan year 2023 and each subsequent plan year, the copayment amount applicable under the preceding sentence to a month’s supply of a selected insulin product (as defined in section 1860D–2(b)(8)(B)) dispensed to the individual..."
may not exceed the applicable copayment or co-
insurance amount for the product under the
prescription drug plan or MA–PD plan in which
the individual is enrolled.”; and

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

(2) in paragraph (2)—

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

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

SEC. 202. ADDITIONAL PROTECTIONS UNDER MEDICARE PART D.

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

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

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

“(A) a PDP sponsor offering a prescription drug plan or a Medicare Advantage organi-
40

zation offering an MA–PD plan shall not, and
shall ensure that any entity that provides phar-

macy benefits management services on behalf of
the prescription drug plan or MA–PD plan of-
fered by the sponsor or organization does not,
directly or indirectly, receive from a manufac-
turer of such insulin—

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

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

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

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

SEC. 203. ADMINISTRATION.

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

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

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