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.

Be it enacted by the Senate and House of Representatives 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.

(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 the maximum list price for such insulin during the plan year pursuant to such certification, in accordance with paragraph (1) or (2) of subsection (b);

"(ii) the Secretary responds to the request under clause (i) with a list price for such insulin for the applicable plan year, in accordance with subsection (b); and

"(iii) the manufacturer attests to the Secretary that it will not exceed the list price provided by the Secretary under clause (ii) for the applicable 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, a certification 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 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; and

''(2) the Secretary includes the insulin in the list of certified insulin publicly posted under subsection (e).

''(b) LIST PRICE FOR INITIAL CERTIFICATION.—

''(1) IN GENERAL.—For plan years beginning on or after January 1, 2024, in the case of an insulin that was licensed under section 351 and marketed on or before December 31, 2021, the insulin may be certified under subsection (a)(1)(A) for a plan year if the list price of such insulin for the applicable plan year is not greater than the weighted average negotiated price for the same insulin 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 from manufacturers with respect to plan year 2021.

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

mitting information attesting that the average list price of such insulin for the plan year will not be greater than 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—

"(A) all rapid-acting insulin products;

"(B) all short-acting insulin products;

"(C) all intermediate-acting insulin products;

"(D) all long-acting insulin products; or

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

"(c) WEIGHTED AVERAGE.—For purposes of subsection (b), the following shall apply:

"(1) The weighted average negotiated price described in subsection (b)(1) shall be increased annually in accordance with the consumer price index for all urban consumers (all items; U.S. city average).

"(2) In calculating the weighted average negotiated price for insulin under paragraphs (1) and (2) of subsection (b), the Secretary shall—

"(A) consider separately each insulin with the same dosage form and strength; and

"(B) weight the average negotiated price for such insulin by the number of enrollees in each prescription drug plan and MA–PD plan under part D of title XVIII of the Social Security Act for the applicable year.

"(d) DECERTIFICATION.—The Secretary shall establish 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 (b).

"(e) 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 insulin products 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, with respect to certified insulins—

"(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.—In the case the Secretary decertifies an insulin under subsection (d) during an applicable plan year, the Secretary shall revise the list to remove such insulin.

"(f) 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 data 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 maximum list price that applies under subsection (a)(1) pursuant to the certification, a civil penalty in the amount equal to the difference between such maximum list price for the insulin and the actual wholesale acquisition cost for such insulin, multiplied by the number of units sold at a price above such maximum list 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.

''(g) 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(c)(6)(B) of the Social Security Act.''.

(b) CONFORMING AMENDMENTS FOR DISCLOSURE OF INFORMATION.—(1) Section 1927(b)(3)(D) of the Social Security Act (42 U.S.C. 1396r–8(b)(3)(D)) is amended—

(A) in clause (iv), by striking ''and'' at the end;

(B) in clause (v), by striking the period at the end and inserting ''; and''; and

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

''(i) as the Secretary determines necessary to carry out section 2796 of the Public Health Service Act.''.

(2) Section 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'' before the period at the end.

(3) Section 1860D–15(d)(2)(B) of the Social Security Act (42 U.S.C. 1395w–115(d)(2)(B)) is amended by

inserting ''or section 2796 of the Public Health Service Act'' before the period at the end.

(4) Section 1860D–15(f)(2)(A)(i) of the Social Security Act (42 U.S.C. 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(c)(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 impose any prior authorization or 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 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3(c)(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 or health insurance 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(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3(c)(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 insur-

ance 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 li-

censed 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 (e) 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 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.''.

(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.—

(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.), as 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 sub-

section (e) 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 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.''.

(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.), as amended by section 102(b)(2), is further amended by inserting after the item relating to section 726 the following:

''Sec. 727. Requirements with respect to cost-sharing for certain insulin products.''.

(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 (e) of such section during the plan year, but only with respect to in-

dividuals 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.

"(c) 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. 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. 105. 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.—The term 'selected insulin products'—

"(aa) 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 a form is licensed 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, includes—

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

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

"(II) ONLY COVERED PART D DRUGS.—The term 'selected insulin products' only includes insulin that is a covered part D drug (and does on include insulin that is covered under part B).

"(III) CLARIFICATIONS.—

"(aa) CERTIFIED INSULIN.—Insulin described in sub-

clause (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 coinsurance 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 subparagraph (B) of such section)''; and

(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 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.''; 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 organization offering an MA–PD plan shall not, and shall ensure that any entity that provides pharmacy benefits management services on behalf of

the prescription drug plan or MA–PD plan offered by the sponsor or organization does not, directly or indirectly, receive from a manufacturer 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 prescription drug plan or a Medicare Advantage organization offering an MA–PD plan shall not impose any prior authorization or other utilization management requirements on such insulin, except as clinically justified for safety reasons, to ensure reasonable quantity limits and as specified 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 remuneration that serves to reduce the cost of prescription drug costs incurred by the PDP sponsor offering the prescription drug plan or the Medicare Advantage 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 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.

(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.