

117TH CONGRESS  
2D SESSION

**S.** \_\_\_\_\_

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

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IN THE SENATE OF THE UNITED STATES

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

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## **A BILL**

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

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

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

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

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

Sec. 1. Short title; table of contents.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

2 “(cc) all intermediate-acting insulin  
3 products;

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

5 or

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

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

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

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

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

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

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

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

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

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

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

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

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

18          “(d) PUBLIC POSTING.—

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

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

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

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

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

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

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

12           or

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

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

20           “(e) AUDITS AND PENALTIES.—

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

1           “(2) PENALTIES.—

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

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

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

5           “(f) DEFINITIONS.—In this section:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

11       “(b) DEFINITIONS.—In this section:

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

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

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

25       (b) ERISA.—

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

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

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

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

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

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

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

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

10          “(b) DEFINITIONS.—In this section:

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

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

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

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

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

6           (c) INTERNAL REVENUE CODE.—

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

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

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

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

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

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

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

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

12          “(b) DEFINITIONS.—In this section:

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

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

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

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

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

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

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

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

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

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

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

23 “(1) apply any deductible; or

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

1           “(A) \$35; or

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

10       “(b) DEFINITIONS.—In this section:

11       “(1) SELECTED INSULIN PRODUCTS.—

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

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

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

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

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

16           “(B) CLARIFICATIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

22 (d) ERISA.—

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

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

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

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

10                   “(1) apply any deductible; or

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

13                           “(A) \$35; or

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

22           “(b) DEFINITIONS.—In this section:

23                   “(1) SELECTED INSULIN PRODUCTS.—

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

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

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

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

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

1 plan or coverage before such decerti-  
2 fication.

3 “(B) CLARIFICATIONS.—

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

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

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

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

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

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

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

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

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

22 (e) INTERNAL REVENUE CODE.—

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

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

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

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

9                   “(1) apply any deductible; or

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

12                           “(A) \$35; or

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

21           “(b) DEFINITIONS.—In this section:

22                   “(1) SELECTED INSULIN PRODUCTS.—

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

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

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

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

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

25 “(B) CLARIFICATIONS.—

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

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

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

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

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

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

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

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

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

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

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

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

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

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

15 **SEC. 106. ADMINISTRATION.**

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

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

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

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

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

10 (1) in subsection (b)—

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

15 (B) in paragraph (2)—

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

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

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

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

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

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

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

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

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

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

24 “(ii) MAXIMUM COST-SHARING.—



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

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

5 “(i) SELECTED INSULIN PRODUCTS.—

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

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

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

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

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

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

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

25 “(III) CLARIFICATIONS.—

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

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

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

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

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

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

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

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

18 (1) in paragraph (1)—

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

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

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

10          (2) in paragraph (2)—

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

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

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

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

13 **PART D.**

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

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

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

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

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

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

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

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

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

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

4 **SEC. 203. ADMINISTRATION.**

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

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

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