

117TH CONGRESS  
2D SESSION

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

To provide for appropriate cost-sharing for insulin products covered under Medicare part D and private health plans.

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IN THE SENATE OF THE UNITED STATES

Mr. WARNOCK (for himself, Mr. SCHUMER, Mr. DURBIN, Mr. WYDEN, Mr. BENNET, Mr. BLUMENTHAL, Ms. BALDWIN, Mr. KELLY, Ms. STABENOW, Mr. REED, Mr. VAN HOLLEN, Ms. HIRONO, Ms. KLOBUCHAR, Mr. MURPHY, Ms. HASSAN, Mrs. SHAHEEN, Mr. BOOKER, Mr. KING, Ms. SMITH, and Mr. PADILLA) introduced the following bill; which was read twice and referred to the Committee on \_\_\_\_\_

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**A BILL**

To provide for appropriate cost-sharing for insulin products covered under Medicare part D and private health plans.

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.**

4 This Act may be cited as the “Affordable Insulin Now  
5 Act”.

1 **SEC. 2. APPROPRIATE COST-SHARING FOR INSULIN PROD-**  
2 **UCTS COVERED UNDER MEDICARE PART D**  
3 **AND PRIVATE HEALTH PLANS.**

4 (a) MEDICARE PART D.—

5 (1) IN GENERAL.—Section 1860D–2 of the So-  
6 cial Security Act (42 U.S.C. 1395w–102) is amend-  
7 ed—

8 (A) in subsection (b)—

9 (i) in paragraph (1)(A), in the matter  
10 preceding clause (i), by striking “The cov-  
11 erage” and inserting “Subject to para-  
12 graph (8), the coverage”;

13 (ii) in paragraph (2)—

14 (I) in subparagraph (A), in the  
15 matter preceding clause (i), by strik-  
16 ing “and (D)” and inserting “and (D)  
17 and paragraph (8)”;

18 (II) in subparagraph (C)(i), in  
19 the matter preceding subclause (I), by  
20 striking “paragraph (4)” and insert-  
21 ing “paragraphs (4) and (8)”;

22 (III) in subparagraph (D)(i), in  
23 the matter preceding subclause (I), by  
24 striking “paragraph (4)” and insert-  
25 ing “paragraphs (4) and (8)”;

1 (iii) in paragraph (3)(A), in the mat-  
2 ter preceding clause (i), by striking “and  
3 (4)” and inserting “(4), and (8)”;

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

8 (v) by adding at the end the following  
9 new paragraph:

10 “(8) TREATMENT OF COST-SHARING FOR COV-  
11 ERED INSULIN PRODUCTS.—

12 “(A) IN GENERAL.—For the portion of  
13 plan year 2022 beginning on October 1, 2022,  
14 and ending on December 31, 2022, and for  
15 plan year 2023 and subsequent plan years, the  
16 following rules shall apply with respect to cost-  
17 sharing for a month’s supply of any covered in-  
18 sulin product (as defined in subparagraph (B))  
19 that is covered under the prescription drug plan  
20 or MA-PD plan:

21 “(i) NO APPLICATION OF DEDUCT-  
22 IBLE.—The deductible under paragraph  
23 (1) shall not apply with respect to any  
24 such covered insulin product.

25 “(ii) MAXIMUM COST-SHARING.—

1                   “(I) IN GENERAL.—The coverage  
2 shall provide benefits for such any  
3 covered insulin product, regardless of  
4 whether an individual has reached the  
5 initial coverage limit under paragraph  
6 (3) or the annual out-of-pocket  
7 threshold under paragraph (4), with  
8 cost-sharing for a month’s supply that  
9 does not exceed the maximum cost-  
10 sharing amount.

11                   “(II) MAXIMUM COST-SHARING  
12 AMOUNT.—For purposes of subclause  
13 (I), the term ‘maximum cost-sharing  
14 amount’ means, with respect to a cov-  
15 ered insulin product under a prescrip-  
16 tion drug plan or an MA–PD plan  
17 dispensed—

18                   “(aa) on or after October 1,  
19 2022, and before January 1,  
20 2024, \$35; and

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

24                   “(AA) \$35; or

1 “(BB) an amount equal  
2 to 25 percent of the nego-  
3 tiated price of the covered  
4 insulin product under the  
5 prescription drug plan or  
6 MA–PD plan.

7 “(B) COVERED INSULIN PRODUCT.—For  
8 purposes of this paragraph, the term ‘covered  
9 insulin product’ means a covered part D drug  
10 that is an insulin product that is approved  
11 under section 505 of the Federal Food, Drug,  
12 and Cosmetic Act or licensed under section 351  
13 of the Public Health Service Act and continues  
14 to be marketed, including any insulin product  
15 that has been deemed to be licensed under sec-  
16 tion 351 of the Public Health Service Act pur-  
17 suant to section 7002(e)(4) of the Biologics  
18 Price Competition and Innovation Act of 2009  
19 and continues to be marketed.”; and

20 (B) in subsection (c), by adding at the end  
21 the 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           (2) CONFORMING AMENDMENTS TO COST-SHAR-  
2           ING FOR LOW-INCOME INDIVIDUALS.—Section  
3           1860D–14(a) of the Social Security Act (42 U.S.C.  
4           1395w–114(a)) is amended—

5                   (A) in paragraph (1)—

6                           (i) in subparagraph (D)(iii), by add-  
7                           ing at the end the following new sentence:  
8                           “For the portion of plan year 2022 begin-  
9                           ning on October 1, 2022, and ending on  
10                           December 31, 2022, and for plan year  
11                           2023 and subsequent plan years, the co-  
12                           payment amount applicable under the pre-  
13                           ceding sentence to a month’s supply of a  
14                           covered insulin product (as described in  
15                           section 1860D–2(b)(8)) dispensed to the  
16                           individual may not exceed the applicable  
17                           copayment or coinsurance amount for the  
18                           product under the prescription drug plan  
19                           or MA–PD plan in which the individual is  
20                           enrolled.”; and

21                           (ii) in subparagraph (E), by inserting  
22                           the following before the period at the end:  
23                           “or under section 1860D–2(b)(8) in the  
24                           case of a covered insulin product (as de-  
25                           scribed in such section)”; and

1 (B) in paragraph (2)—

2 (i) in subparagraph (D), by adding at  
3 the end the following new sentence: “For  
4 the portion of plan year 2022 beginning on  
5 October 1, 2022, and ending on December  
6 31, 2022, and for plan year 2023 and sub-  
7 sequent plan years, the amount of the co-  
8 insurance applicable under the preceding  
9 sentence to a month’s supply of a covered  
10 insulin product (as described in section  
11 1860D–2(b)(8)) dispensed to the indi-  
12 vidual may not exceed the applicable co-  
13 payment or coinsurance amount for the  
14 product under the prescription drug plan  
15 or MA–PD plan in which the individual is  
16 enrolled.”; and

17 (ii) in subparagraph (E), by adding at  
18 the end the following new sentence: “For  
19 the portion of plan year 2022 beginning on  
20 October 1, 2022, and ending on December  
21 31, 2022, and for plan year 2023 and sub-  
22 sequent plan years, the amount of the co-  
23 payment or coinsurance applicable under  
24 the preceding sentence to a month’s supply  
25 of a covered insulin product (as described

1 in section 1860D–2(b)(8)) dispensed to the  
2 individual may not exceed the applicable  
3 copayment or coinsurance amount for the  
4 product under the prescription drug plan  
5 or MA–PD plan in which the individual is  
6 enrolled.”.

7 (3) IMPLEMENTATION.—Notwithstanding any  
8 other provision of law, the Secretary of Health and  
9 Human Services may implement the provisions of,  
10 including the amendments made by, this subsection  
11 for plan years 2022, 2023, and 2024 by program in-  
12 struction or otherwise.

13 (4) FUNDING.—In addition to amounts other-  
14 wise available, there is appropriated to the Centers  
15 for Medicare & Medicaid Services, out of any money  
16 in the Treasury not otherwise appropriated,  
17 \$1,500,000 for fiscal year 2022, to remain available  
18 until expended, to carry out the provisions of, in-  
19 cluding the amendments made by, this subsection.

20 (b) PRIVATE HEALTH PLANS.—

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



1 **“SEC. 2799A-11. REQUIREMENTS WITH RESPECT TO COST-**  
2 **SHARING FOR CERTAIN INSULIN PRODUCTS.**

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

8 “(1) apply any deductible; or

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

11 “(A) \$35; or

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

20 “(b) DEFINITIONS.—In this section:

21 “(1) SELECTED INSULIN PRODUCTS.—The term  
22 ‘selected insulin products’ means at least one of each  
23 dosage form (such as vial, pump, or inhaler dosage  
24 forms) of each different type (such as rapid-acting,  
25 short-acting, intermediate-acting, long-acting, ultra  
26 long-acting, and premixed) of insulin (as defined

1 below), when available, as selected by the group  
2 health plan or health insurance issuer.

3 “(2) INSULIN DEFINED.—The term ‘insulin’  
4 means insulin that is licensed under subsection (a)  
5 or (k) of section 351 and continues to be marketed  
6 under such section, including any insulin product  
7 that has been deemed to be licensed under section  
8 351(a) pursuant to section 7002(e)(4) of the Bio-  
9 logics Price Competition and Innovation Act of 2009  
10 and continues to be marketed pursuant to such li-  
11 censure.

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

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

1 ucts, to the extent that such coverage is not otherwise re-  
2 quired and such cost-sharing is otherwise permitted under  
3 Federal and applicable State law.

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

9 (2) NO EFFECT ON OTHER COST-SHARING.—  
10 Section 1302(d)(2) of the Patient Protection and Af-  
11 fordable Care Act (42 U.S.C. 18022(d)(2)) is  
12 amended by adding at the end the following new  
13 subparagraph:

14 “(D) SPECIAL RULE RELATING TO INSU-  
15 LIN COVERAGE.—The exemption of coverage of  
16 selected insulin products (as defined in section  
17 2799A–11(b) of the Public Health Service Act)  
18 from the application of any deductible pursuant  
19 to section 2799A–11(a)(1) of such Act, section  
20 726(a)(1) of the Employee Retirement Income  
21 Security Act of 1974, or section 9826(a)(1) of  
22 the Internal Revenue Code of 1986 shall not be  
23 considered when determining the actuarial value  
24 of a qualified health plan under this sub-  
25 section.”.

1           (3) COVERAGE OF CERTAIN INSULIN PRODUCTS  
2 UNDER CATASTROPHIC PLANS.—Section 1302(e) of  
3 the Patient Protection and Affordable Care Act (42  
4 U.S.C. 18022(e)) is amended by adding at the end  
5 the following:

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

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

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

19           “(i) the term ‘selected insulin prod-  
20 ucts’ has the meaning given such term in  
21 section 2799A–11(b) of the Public Health  
22 Service Act; and

23           “(ii) the requirements of section  
24 2799A–11 of such Act shall be applied by  
25 deeming each reference in such section to

1           ‘individual health insurance coverage’ to be  
2           a reference to a plan described in para-  
3           graph (1).”.

4           (4) ERISA.—

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

10   **“SEC. 726. REQUIREMENTS WITH RESPECT TO COST-SHAR-**  
11           **ING FOR CERTAIN INSULIN PRODUCTS.**

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

17                   “(1) apply any deductible; or

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

20                           “(A) \$35; or

21                           “(B) the amount equal to 25 percent of  
22           the negotiated price of the selected insulin prod-  
23           uct net of all price concessions received by or on  
24           behalf of the plan or coverage, including price  
25           concessions received by or on behalf of third-

1 party entities providing services to the plan or  
2 coverage, such as pharmacy benefit manage-  
3 ment services.

4 “(b) DEFINITIONS.—In this section:

5 “(1) SELECTED INSULIN PRODUCTS.—The term  
6 ‘selected insulin products’ means at least one of each  
7 dosage form (such as vial, pump, or inhaler dosage  
8 forms) of each different type (such as rapid-acting,  
9 short-acting, intermediate-acting, long-acting, ultra  
10 long-acting, and premixed) of insulin (as defined  
11 below), when available, as selected by the group  
12 health plan or health insurance issuer.

13 “(2) INSULIN DEFINED.—The term ‘insulin’  
14 means insulin that is licensed under subsection (a)  
15 or (k) of section 351 of the Public Health Service  
16 Act (42 U.S.C. 262) and continues to be marketed  
17 under such section, including any insulin product  
18 that has been deemed to be licensed under section  
19 351(a) of such Act pursuant to section 7002(e)(4)  
20 of the Biologics Price Competition and Innovation  
21 Act of 2009 (Public Law 111–148) and continues to  
22 be marketed pursuant to such licensure.

23 “(c) OUT-OF-NETWORK PROVIDERS.—Nothing in  
24 this section requires a plan or issuer that has a network  
25 of providers to provide benefits for selected insulin prod-

1 ucts described in this section that are delivered by an out-  
2 of-network provider, or precludes a plan or issuer that has  
3 a network of providers from imposing higher cost-sharing  
4 than the levels specified in subsection (a) for selected insu-  
5 lin products described in this section that are delivered  
6 by an out-of-network provider.

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

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

20 (B) **CLERICAL AMENDMENT.**—The table of  
21 contents in section 1 of the Employee Retirement  
22 Income Security Act of 1974 (29 U.S.C.  
23 1001 et seq.) is amended by inserting after the  
24 item relating to section 725 the following:

“Sec. 726. Requirements with respect to cost-sharing for certain insulin prod-  
ucts.”.

1 (5) INTERNAL REVENUE CODE.—

2 (A) IN GENERAL.—Subchapter B of chap-  
3 ter 100 of the Internal Revenue Code of 1986  
4 is amended by adding at the end the following  
5 new section:

6 **“SEC. 9826. REQUIREMENTS WITH RESPECT TO COST-SHAR-**  
7 **ING FOR CERTAIN INSULIN PRODUCTS.**

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

12 “(1) apply any deductible; or

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

15 “(A) \$35; or

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

23 “(b) DEFINITIONS.—In this section:

24 “(1) SELECTED INSULIN PRODUCTS.—The term  
25 ‘selected insulin products’ means at least one of each



1 dosage form (such as vial, pump, or inhaler dosage  
2 forms) of each different type (such as rapid-acting,  
3 short-acting, intermediate-acting, long-acting, ultra  
4 long-acting, and premixed) of insulin (as defined  
5 below), when available, as selected by the group  
6 health plan.

7 “(2) INSULIN DEFINED.—The term ‘insulin’  
8 means insulin that is licensed under subsection (a)  
9 or (k) of section 351 of the Public Health Service  
10 Act (42 U.S.C. 262) and continues to be marketed  
11 under such section, including any insulin product  
12 that has been deemed to be licensed under section  
13 351(a) of such Act pursuant to section 7002(e)(4)  
14 of the Biologics Price Competition and Innovation  
15 Act of 2009 (Public Law 111–148) and continues to  
16 be marketed pursuant to such licensure.

17 “(c) OUT-OF-NETWORK PROVIDERS.—Nothing in  
18 this section requires a plan that has a network of providers  
19 to provide benefits for selected insulin products described  
20 in this section that are delivered by an out-of-network pro-  
21 vider, or precludes a plan that has a network of providers  
22 from imposing higher cost-sharing than the levels specified  
23 in subsection (a) for selected insulin products described  
24 in this section that are delivered by an out-of-network pro-  
25 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                           (B) CLERICAL AMENDMENT.—The table of  
15 sections for subchapter B of chapter 100 of  
16 such Code is amended by adding at the end the  
17 following new item:

“Sec. 9826. Requirements with respect to cost-sharing for certain insulin prod-  
ucts.”.

18           (6) IMPLEMENTATION.—The Secretary of  
19 Health and Human Services, the Secretary of Labor,  
20 and the Secretary of the Treasury may implement  
21 the provisions of, including the amendments made  
22 by, this subsection through sub-regulatory guidance,  
23 program instruction or otherwise.