

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

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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 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”.

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

9 (a) MEDICARE PART D.—

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

4                   (A) in subsection (b)—

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

9                           (ii) in paragraph (2)(A), in the matter  
10                          preceding clause (i), by striking “and (D)”  
11                          and inserting “and (D) and paragraph  
12                          (8)”;

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

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

20                          (v) by adding at the end the following  
21                          new paragraph:

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

24                               “(A) IN GENERAL.—For the portion of  
25                               plan year 2022 beginning on October 1, 2022,

1 and ending on December 31, 2022, and for  
2 plan year 2023 and subsequent plan years, the  
3 following rules shall apply with respect to cost-  
4 sharing for covered insulin products (as defined  
5 in subparagraph (B)):

6 “(i) NO APPLICATION OF DEDUCT-  
7 IBLE.—The deductible under paragraph  
8 (1) shall not apply with respect to such  
9 covered insulin products.

10 “(ii) MAXIMUM COST-SHARING  
11 AMOUNT.—

12 “(I) IN GENERAL.—The coverage  
13 shall provide benefits for such covered  
14 insulin products, regardless of wheth-  
15 er an individual has reached the ini-  
16 tial coverage limit under paragraph  
17 (3) or the annual out-of-pocket  
18 threshold under paragraph (4), with  
19 cost-sharing that does not exceed the  
20 maximum cost-sharing amount.

21 “(II) MAXIMUM COST-SHARING  
22 AMOUNT.—For purposes of subclause  
23 (I), the term ‘maximum cost-sharing  
24 amount’ means, with respect to a cov-  
25 ered insulin product under a prescrip-

1                   tion drug plan or an MA–PD, the  
2                   lesser of—

3                                   “(aa) \$35; or

4                                   “(bb) an amount equal to 25  
5                                   percent of the negotiated price of  
6                                   the covered insulin product under  
7                                   the prescription drug plan or  
8                                   MA–PD plan.

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

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

23                                   “(4) TREATMENT OF COST-SHARING FOR INSU-  
24                   LIN PRODUCTS.—The coverage is provided in accord-  
25                   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 an insulin product (as  
14      defined in section 1860D–2(b)(8)) fur-  
15      nished to the individual may not exceed the  
16      applicable copayment or coinsurance  
17      amount for the product under the prescrip-  
18      tion drug plan or MA–PD plan in which  
19      the individual is enrolled.”; and

20          (ii) in subparagraph (E), by inserting  
21      the following before the period at the end:  
22      “or under section 1860D–2(b)(9) in the  
23      case of an insulin product (as defined in  
24      subparagraph (D) of such section)”; and

25          (B) in paragraph (2)—

1 (i) in subparagraph (D), by adding at  
2 the end the following new sentence: “For  
3 the portion of plan year 2022 beginning on  
4 October1, 2022, and ending on December  
5 31, 2022, and for plan year 2023 and sub-  
6 sequent plan years, the amount of the co-  
7 insurance applicable under the preceding  
8 sentence to an insulin product (as defined  
9 in section 1860D–2(b)(8)) furnished to the  
10 individual may not exceed the applicable  
11 copayment or coinsurance amount for the  
12 product under the prescription drug plan  
13 or MA–PD plan in which the individual is  
14 enrolled.”; and

15 (ii) in subparagraph (E), by adding at  
16 the end the following new sentence: “For  
17 the portion of plan year 2022 beginning on  
18 October 1, 2022, and ending on December  
19 31, 2022, and for plan year 2023 and sub-  
20 sequent plan years, the amount of the co-  
21 payment or coinsurance applicable under  
22 the preceding sentence to an insulin prod-  
23 uct (as defined in section 1860D–2(b)(8))  
24 furnished to the individual may not exceed  
25 the applicable copayment or coinsurance

1 amount for the product under the prescrip-  
2 tion drug plan or MA–PD plan in which  
3 the individual is enrolled.”.

4 (3) IMPLEMENTATION.—The Secretary of  
5 Health and Human Services may implement the pro-  
6 visions of, and the amendments made by, this sub-  
7 section for plan years 2022 and 2023 by program  
8 instruction.

9 (b) PRIVATE HEALTH PLANS.—

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

13 **“SEC. 2799A–11. REQUIREMENTS WITH RESPECT TO COST-**  
14 **SHARING FOR CERTAIN INSULIN PRODUCTS.**

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

20 “(1) apply any deductible; or

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

23 “(A) \$35; or

24 “(B) the amount equal to 25 percent of  
25 the negotiated price of the selected insulin prod-

1           uct net of all price concessions received by or on  
2           behalf of the plan or coverage, including price  
3           concessions received by or on behalf of third-  
4           party entities providing services to the plan or  
5           coverage, such as pharmacy benefit manage-  
6           ment services.

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

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

16                “(2) INSULIN DEFINED.—The term ‘insulin’  
17          means insulin that is licensed under subsection (a)  
18          or (k) of section 351 and continues to be marketed  
19          under such section, including any insulin product  
20          that has been deemed to be licensed under section  
21          351(a) pursuant to section 7002(e)(4) of the Bio-  
22          logics Price Competition and Innovation Act of 2009  
23          and continues to be marketed pursuant to such li-  
24          censure.



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

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

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

23           (2) NO EFFECT ON OTHER COST-SHARING.—  
24           Section 1302(d)(2) of the Patient Protection and Af-  
25           fordable Care Act (42 U.S.C. 18022(d)(2)) is

1 amended by adding at the end the following new  
2 subparagraph:

3 “(D) SPECIAL RULE RELATING TO INSU-  
4 LIN COVERAGE.—The exemption of coverage of  
5 selected insulin products (as defined in section  
6 2799A–11(b) of the Public Health Service Act)  
7 from the application of any deductible pursuant  
8 to section 2799A–11(a)(1) of such Act, section  
9 726(a)(1) of the Employee Retirement Income  
10 Security Act of 1974, or section 9826(a)(1) of  
11 the Internal Revenue Code of 1986 shall not be  
12 considered when determining the actuarial value  
13 of a qualified health plan under this sub-  
14 section.”.

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

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

22 “(A) IN GENERAL.—Notwithstanding para-  
23 graph (1)(B)(i), a health plan described in  
24 paragraph (1) shall provide coverage of selected  
25 insulin products, in accordance with section

1           2799A–11 of the Public Health Service Act, for  
2           a plan year before an enrolled individual has in-  
3           curred cost-sharing expenses in an amount  
4           equal to the annual limitation in effect under  
5           subsection (c)(1) for the plan year.

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

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

12                   “(ii) the requirements of section  
13                  2799A–11 of such Act shall be applied by  
14                  deeming each reference in such section to  
15                  ‘individual health insurance coverage’ to be  
16                  a reference to a plan described in para-  
17                  graph (1).”.

18           (4) ERISA.—

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

1 **“SEC. 726. REQUIREMENTS WITH RESPECT TO COST-SHAR-**  
2 **ING 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 health insurance coverage  
6 shall provide coverage of selected insulin products, and  
7 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 of the Public Health Service  
6 Act (42 U.S.C. 262) and continues to be marketed  
7 under such section, including any insulin product  
8 that has been deemed to be licensed under section  
9 351(a) of such Act pursuant to section 7002(e)(4)  
10 of the Biologics Price Competition and Innovation  
11 Act of 2009 (Public Law 111–148) and continues to  
12 be marketed pursuant to such licensure.

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

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

1 (a) on, insulin products that are not selected insulin prod-  
 2 ucts, to the extent that such coverage is not otherwise re-  
 3 quired and such cost-sharing is otherwise permitted under  
 4 Federal and applicable State law.

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

10 (B) CLERICAL AMENDMENT.—The table of  
 11 contents in section 1 of the Employee Retirement  
 12 Income Security Act of 1974 (29 U.S.C.  
 13 1001 et seq.) is amended by inserting after the  
 14 item relating to section 725 the following:

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

15 (5) INTERNAL REVENUE CODE.—

16 (A) IN GENERAL.—Subchapter B of chap-  
 17 ter 100 of the Internal Revenue Code of 1986  
 18 is amended by adding at the end the following  
 19 new section:

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

22 “(a) IN GENERAL.—For plan years beginning on or  
 23 after January 1, 2023, a group health plan shall provide

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

3 “(1) apply any deductible; or

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

6 “(A) \$35; or

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

14 “(b) DEFINITIONS.—In this section:

15 “(1) SELECTED INSULIN PRODUCTS.—The term  
16 ‘selected insulin products’ means at least one of each  
17 dosage form (such as vial, pump, or inhaler dosage  
18 forms) of each different type (such as rapid-acting,  
19 short-acting, intermediate-acting, long-acting, ultra  
20 long-acting, and premixed) of insulin (as defined  
21 below), when available, as selected by the group  
22 health plan.

23 “(2) INSULIN DEFINED.—The term ‘insulin’  
24 means insulin that is licensed under subsection (a)  
25 or (k) of section 351 of the Public Health Service

1 Act (42 U.S.C. 262) and continues to be marketed  
2 under such section, including any insulin product  
3 that has been deemed to be licensed under section  
4 351(a) of such Act pursuant to section 7002(e)(4)  
5 of the Biologics Price Competition and Innovation  
6 Act of 2009 (Public Law 111–148) and continues to  
7 be marketed pursuant to such licensure.

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

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



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

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

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