

117TH CONGRESS
2D SESSION

S. 3700

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

IN THE SENATE OF THE UNITED STATES

FEBRUARY 17, 2022

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 Finance

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)”; and

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 ment 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.

○