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AN ACT

To amend title XXVII of the Public Health Service Act, the Internal Revenue Code of 1986, and the Employee Retirement Income Security Act of 1974 to establish requirements with respect to cost-sharing for certain insulin products, and for other purposes.

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. REQUIREMENTS WITH RESPECT TO COST-SHARING**
2 **FOR INSULIN PRODUCTS.**

3 (a) PHSA.—Part D of title XXVII of the Public
4 Health Service Act (42 U.S.C. 300gg–111 et seq.) is
5 amended by adding at the end the following new section:

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

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

13 “(1) apply any deductible; or

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

16 “(A) \$35; or

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

25 “(b) DEFINITIONS.—In this section:

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

9 “(2) INSULIN DEFINED.—The term ‘insulin’
10 means insulin that is licensed under subsection (a)
11 or (k) of section 351 and continues to be marketed
12 under such section, including any insulin product
13 that has been deemed to be licensed under section
14 351(a) pursuant to section 7002(e)(4) of the Bio-
15 logics Price Competition and Innovation Act of 2009
16 and continues to be marketed pursuant to such li-
17 censure.

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

17 (1) **IN GENERAL.**—Subchapter B of chapter
18 100 of the Internal Revenue Code of 1986 is amend-
19 ed by adding at the end the following 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
24 coverage of selected insulin products and, with respect to
25 such products, shall not—

1 “(1) apply any deductible; or

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

4 “(A) \$35; or

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

12 “(b) DEFINITIONS.—In this section:

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

21 “(2) INSULIN DEFINED.—The term ‘insulin’
22 means insulin that is licensed under subsection (a)
23 or (k) of section 351 of the Public Health Service
24 Act and continues to be marketed under such sec-
25 tion, including any insulin product that has been

1 deemed to be licensed under section 351(a) of such
2 Act pursuant to section 7002(e)(4) of the Biologics
3 Price Competition and Innovation Act of 2009 and
4 continues to be marketed pursuant to such licensure.

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

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

22 “(e) APPLICATION OF COST-SHARING TOWARDS
23 DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any
24 cost-sharing payments made pursuant to subsection (a)(2)

1 shall be counted toward any deductible or out-of-pocket
2 maximum that applies under the plan.”.

3 (2) CLERICAL AMENDMENT.—The table of sec-
4 tions for subchapter B of chapter 100 of the Inter-
5 nal Revenue Code of 1986 is amended by adding at
6 the end the following new item:

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

7 (c) ERISA.—

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

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

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

19 “(1) apply any deductible; or

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

22 “(A) \$35; or

23 “(B) the amount equal to 25 percent of
24 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 of the Public Health Service
19 Act and continues to be marketed under such sec-
20 tion, including any insulin product that has been
21 deemed to be licensed under section 351(a) of such
22 Act pursuant to section 7002(e)(4) of the Biologics
23 Price Competition and Innovation Act of 2009 and
24 continues to be marketed pursuant to such licensure.

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) CLERICAL AMENDMENT.—The table of con-
24 tents in section 1 of the Employee Retirement In-
25 come Security Act of 1974 (29 U.S.C. 1001 et seq.)

1 is amended by inserting after the item relating to
2 section 725 the following:

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

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

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

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

23 “(4) COVERAGE OF CERTAIN INSULIN PROD-
24 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–11 of the Public Health Service Act, be-
6 fore an enrolled individual has incurred, during
7 a plan year, cost-sharing expenses in an amount
8 equal to the annual limitation in effect under
9 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–11(b) of the Public Health
15 Service Act; and

16 “(ii) the requirements of section
17 2799A–11 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 (f) IMPLEMENTATION.—The Secretary of Health and
23 Human Services, the Secretary of Labor, and the Sec-
24 retary of the Treasury may implement the provisions of,
25 including the amendments made by, this section through

1 sub-regulatory guidance, program instruction, or other-
2 wise.

3 **SEC. 3. APPROPRIATE COST-SHARING FOR CERTAIN INSU-**
4 **LIN PRODUCTS UNDER MEDICARE PART D.**

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

7 (1) in subsection (b)—

8 (A) in paragraph (1)(A), by striking “The
9 coverage” and inserting “Subject to paragraph
10 (8), the coverage”;

11 (B) in paragraph (2)—

12 (i) in subparagraph (A), by striking
13 “and (D)” and inserting “and (D) and
14 paragraph (8)”;

15 (ii) in subparagraph (B), by striking
16 “and (D)” and inserting “and (D) and
17 paragraph (8)”;

18 (iii) in subparagraph (C)(i), by strik-
19 ing “paragraph (4)” and inserting “para-
20 graphs (4) and (8)”;

21 (iv) in subparagraph (D)(i), by strik-
22 ing “paragraph (4)” and inserting “para-
23 graphs (4) and (8)”;

24 (C) in paragraph (3)(A), by striking “and
25 (4)” and inserting “(4), and (8)”;

1 (D) in paragraph (4)(A)(i), by striking
2 “The coverage” and inserting “Subject to para-
3 graph (8), the coverage”; and

4 (E) by adding at the end the following new
5 paragraph:

6 “(8) TREATMENT OF COST-SHARING FOR CER-
7 TAIN INSULIN PRODUCTS.—

8 “(A) IN GENERAL.—For plan years begin-
9 ning on or after January 1, 2023, with respect
10 to an individual, the following shall apply with
11 respect to any insulin product (as defined in
12 subparagraph (B)) that is covered under the
13 prescription drug plan or MA–PD plan in which
14 the individual is enrolled:

15 “(i) NO APPLICATION OF DEDUCT-
16 IBLE.—The deductible under paragraph
17 (1) shall not apply with respect to such in-
18 sulin product.

19 “(ii) APPLICATION OF COST-SHAR-
20 ING.—

21 “(I) IN GENERAL.—The coverage
22 provides benefits for such insulin
23 product, regardless of whether an in-
24 dividual has reached the initial cov-
25 erage limit under paragraph (3) or

1 the out-of-pocket threshold under
2 paragraph (4), with cost-sharing for a
3 one-month supply that is equal to the
4 applicable copayment amount.

5 “(II) APPLICABLE COPAYMENT
6 AMOUNT.—For purposes of this
7 clause, the term ‘applicable copayment
8 amount’ means, with respect to an in-
9 sulin product under a prescription
10 drug plan or an MA–PD plan, an
11 amount that is not more than \$35.

12 “(B) INSULIN PRODUCT.—For purposes of
13 this paragraph, the term ‘insulin product’
14 means a covered part D drug that is an insulin
15 product that is approved under section 505 of
16 the Federal Food, Drug, and Cosmetic Act or
17 licensed under section 351 of the Public Health
18 Service Act and marketed pursuant to such ap-
19 proval or licensure, including any insulin prod-
20 uct that has been deemed to be licensed under
21 section 351 of the Public Health Service Act
22 pursuant to section 7002(e)(4) of the Biologics
23 Price Competition and Innovation Act of 2009
24 and marketed pursuant to such section.”; and

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

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

6 (b) CONFORMING AMENDMENTS TO COST-SHARING
7 FOR LOW-INCOME INDIVIDUALS.—Section 1860D–14(a)
8 of the Social Security Act (42 U.S.C. 1395w–114(a)) is
9 amended—

10 (1) in paragraph (1)—

11 (A) in subparagraph (D)(iii), by adding at
12 the end the following new sentence: “For plan
13 year 2023 and subsequent plan years, the co-
14 payment amount applicable under the preceding
15 sentence for a one-month supply of an insulin
16 product (as defined in subparagraph (B) of sec-
17 tion 1860D–2(b)(8)) dispensed to the individual
18 may not exceed the applicable copayment
19 amount (as defined in subparagraph (A)(ii)(II)
20 of such section) for the product under the pre-
21 scription drug plan or MA–PD plan in which
22 the individual is enrolled.”; and

23 (B) in subparagraph (E), by inserting the
24 following before the period at the end “or under
25 section 1860D–2(b)(8) in the case of an insulin

1 product (as defined in subparagraph (B) of
2 such section)”; and

3 (2) in paragraph (2)—

4 (A) in subparagraph (B), by adding at the
5 end the following new sentence: “For plan year
6 2023 and subsequent plan years, the annual de-
7 ductible applicable under such section, including
8 as reduced under the preceding sentence, shall
9 not apply with respect to an insulin product (as
10 defined in subparagraph (B) of section 1860D-
11 2(b)(8)) dispensed to the individual.”;

12 (B) in subparagraph (D), by adding at the
13 end the following new sentence: “For plan year
14 2023 and subsequent plan years, the amount of
15 the coinsurance applicable under the preceding
16 sentence for a one-month supply of an insulin
17 product (as defined in subparagraph (B) of sec-
18 tion 1860D-2(b)(8)) dispensed to the individual
19 may not exceed the applicable copayment
20 amount (as defined in subparagraph (A)(ii)(II)
21 of such section) for the product under the pre-
22 scription drug plan or MA-PD plan in which
23 the individual is enrolled.”; and

24 (C) in subparagraph (E), by adding at the
25 end the following new sentence: “For plan year

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