

117TH CONGRESS
2^D SESSION

H. R. 6833

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,*

1 **SECTION 1. SHORT TITLE.**

2 This Act may be cited as the “Affordable Insulin Now
3 Act”.

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

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

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

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

16 “(1) apply any deductible; or

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

19 “(A) \$35; or

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

1 coverage, such as pharmacy benefit manage-
2 ment services.

3 “(b) DEFINITIONS.—In this section:

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

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

21 “(c) OUT-OF-NETWORK PROVIDERS.—Nothing in
22 this section requires a plan or issuer that has a network
23 of providers to provide benefits for selected insulin prod-
24 ucts described in this section that are delivered by an out-
25 of-network provider, or precludes a plan or issuer that has

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

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

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

18 (b) IRC.—

19 (1) IN GENERAL.—Subchapter B of chapter
20 100 of the Internal Revenue Code of 1986 is amend-
21 ed by adding at the end the following new section:

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

24 “(a) IN GENERAL.—For plan years beginning on or
25 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 and continues to be marketed under such sec-
2 tion, including any insulin product that has been
3 deemed to be licensed under section 351(a) of such
4 Act pursuant to section 7002(e)(4) of the Biologics
5 Price Competition and Innovation Act of 2009 and
6 continues to be marketed pursuant to such licensure.

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

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

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

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

8 (c) ERISA.—

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

13 **“SEC. 726. REQUIREMENTS WITH RESPECT TO COST-SHAR-**
 14 **ING 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 health insurance coverage
 18 shall provide coverage of selected insulin products and,
 19 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

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

9 “(b) DEFINITIONS.—In this section:

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

18 “(2) INSULIN DEFINED.—The term ‘insulin’
19 means insulin that is licensed under subsection (a)
20 or (k) of section 351 of the Public Health Service
21 Act and continues to be marketed under such sec-
22 tion, including any insulin product that has been
23 deemed to be licensed under section 351(a) of such
24 Act pursuant to section 7002(e)(4) of the Biologics

1 Price Competition and Innovation Act of 2009 and
2 continues to be marketed pursuant to such licensure.

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

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

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

1 Patient Protection and Affordable Care Act (42 U.S.C.
2 18022(e)) is amended by adding at the end the following:

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

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

14 “(B) TERMINOLOGY.—For purposes of
15 subparagraph (A)—

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

20 “(ii) the requirements of section
21 2799A–11 of such Act shall be applied by
22 deeming each reference in such section to
23 ‘individual health insurance coverage’ to be
24 a reference to a plan described in para-
25 graph (1).”.

1 (f) IMPLEMENTATION.—The Secretary of Health and
2 Human Services, the Secretary of Labor, and the Sec-
3 retary of the Treasury may implement the provisions of,
4 including the amendments made by, this section through
5 sub-regulatory guidance, program instruction, or other-
6 wise.

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

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

11 (1) in subsection (b)—

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

15 (B) in paragraph (2)—

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

19 (ii) in subparagraph (B), by striking
20 “and (D)” and inserting “and (D) and
21 paragraph (8)”;

22 (iii) in subparagraph (C)(i), by strik-
23 ing “paragraph (4)” and inserting “para-
24 graphs (4) and (8)”;

1 (iv) in subparagraph (D)(i), by strik-
2 ing “paragraph (4)” and inserting “para-
3 graphs (4) and (8)”;

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

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

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

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

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

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

24 “(ii) APPLICATION OF COST-SHAR-
25 ING.—

1 “(I) IN GENERAL.—The coverage
2 provides benefits for such insulin
3 product, regardless of whether an in-
4 dividual has reached the initial cov-
5 erage limit under paragraph (3) or
6 the out-of-pocket threshold under
7 paragraph (4), with cost-sharing for a
8 one-month supply that is equal to the
9 applicable copayment amount.

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

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

1 section 351 of the Public Health Service Act
2 pursuant to section 7002(e)(4) of the Biologics
3 Price Competition and Innovation Act of 2009
4 and marketed pursuant to such section.”; and
5 (2) in subsection (c), by adding at the end the
6 following new paragraph:

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

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

14 (1) in paragraph (1)—

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

1 description drug plan or MA–PD plan in which
2 the individual is enrolled.”; and

3 (B) in subparagraph (E), by inserting the
4 following before the period at the end “or under
5 section 1860D–2(b)(8) in the case of an insulin
6 product (as defined in subparagraph (B) of
7 such section)”; and

8 (2) in paragraph (2)—

9 (A) in subparagraph (B), by adding at the
10 end the following new sentence: “For plan year
11 2023 and subsequent plan years, the annual de-
12 ductible applicable under such section, including
13 as reduced under the preceding sentence, shall
14 not apply with respect to an insulin product (as
15 defined in subparagraph (B) of section 1860D–
16 2(b)(8)) dispensed to the individual.”;

17 (B) in subparagraph (D), by adding at the
18 end the following new sentence: “For plan year
19 2023 and subsequent plan years, the amount of
20 the coinsurance applicable under the preceding
21 sentence for a one-month supply of an insulin
22 product (as defined in subparagraph (B) of sec-
23 tion 1860D–2(b)(8)) dispensed to the individual
24 may not exceed the applicable copayment
25 amount (as defined in subparagraph (A)(ii)(II)

1 of such section) for the product under the pre-
2 scription drug plan or MA–PD plan in which
3 the individual is enrolled.”; and

4 (C) in subparagraph (E), by adding at the
5 end the following new sentence: “For plan year
6 2023 and subsequent plan years, the amount of
7 the copayment or coinsurance applicable under
8 the preceding sentence for a one-month supply
9 of an insulin product (as defined in subpara-
10 graph (B) of section 1860D–2(b)(8)) dispensed
11 to the individual may not exceed the applicable
12 copayment amount (as defined in subparagraph
13 (A)(ii)(II) of such section) for the product
14 under the prescription drug plan or MA–PD
15 plan in which the individual is enrolled.”

16 (c) IMPLEMENTATION.—Notwithstanding any other
17 provision of law, the Secretary of Health and Human
18 Services shall implement this section for plan years 2023
19 and 2024 by program instruction or otherwise.

1 **SEC. 4. ONE YEAR-EXTENSION ON MORATORIUM ON IMPLE-**
2 **MENTATION OF RULE RELATING TO ELIMI-**
3 **NATING THE ANTI-KICKBACK STATUTE SAFE**
4 **HARBOR PROTECTION FOR PRESCRIPTION**
5 **DRUG REBATES.**

6 Section 90006 of the Infrastructure Investment and
7 Jobs Act (P.L. 117–58) is amended by striking “January
8 1, 2026” and inserting “January 1, 2027”.

9 **SEC. 5. MEDICARE IMPROVEMENT FUND.**

10 Section 1898(b)(1) of the Social Security Act (42
11 U.S.C. 1395iii(b)(1)), as amended by section 313 of divi-
12 sion P of the Consolidated Appropriations Act, 2022, is
13 amended by striking “\$5,000,000” and inserting
14 “\$9,046,500,000”.

Passed the House of Representatives March 31,
2022.

Attest:

Clerk.

117TH CONGRESS
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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.