

117<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

# H. R. 6833

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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,*

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.*



117<sup>TH</sup> CONGRESS  
2<sup>D</sup> SESSION

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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.