

118TH CONGRESS  
1ST SESSION

# H. R. 1488

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.

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## IN THE HOUSE OF REPRESENTATIVES

MARCH 9, 2023

Ms. CRAIG (for herself, Mr. KILDEE, and Mrs. MCBATH) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, and Education and the Workforce, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## A BILL

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, 2024, 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, 2024, 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 (42 U.S.C. 262) and continues to be marketed  
25 under such section, including any insulin product

1 that has been deemed to be licensed under section  
2 351(a) of such Act pursuant to section 7002(e)(4)  
3 of the Biologics Price Competition and Innovation  
4 Act of 2009 (Public Law 111–148) and continues to  
5 be marketed pursuant to such licensure.

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

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

23 “(e) APPLICATION OF COST-SHARING TOWARDS  
24 DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any  
25 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, 2024, 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 (42 U.S.C. 262) and continues to be marketed  
20          under such section, including any insulin product  
21          that has been deemed to be licensed under section  
22          351(a) of such Act pursuant to section 7002(e)(4)  
23          of the Biologics Price Competition and Innovation  
24          Act of 2009 (Public Law 111–148) and continues to  
25          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, for  
6 a plan year before an enrolled individual has in-  
7 curred 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).”.

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