117TH CONGRESS
2D 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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the ''Affordable Insulin Now Act''.

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

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

''SEC. 2799A–11. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

''(a) IN GENERAL.—For plan years beginning on or after January 1, 2023, a group health plan or health insurance issuer offering group or individual health insurance coverage shall provide coverage of selected insulin products and, with respect to such products, shall not—

''(1) apply any deductible; or

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

''(A) $35; or

''(B) the amount equal to 25 percent of the negotiated price of the selected insulin product net of all price concessions received by or on behalf of the plan or coverage, including price concessions received by or on behalf of third-party entities providing services to the plan or

coverage, such as pharmacy benefit management services.

''(b) DEFINITIONS.—In this section:

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

''(2) INSULIN DEFINED.—The term 'insulin' means insulin that is licensed under subsection (a) or (k) of section 351 and continues to be marketed under such section, including any insulin product that has been deemed to be licensed under section 351(a) pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 and continues to be marketed pursuant to such licensure.

''(c) OUT-OF-NETWORK PROVIDERS.—Nothing in this section requires a plan or issuer that has a network of providers to provide benefits for selected insulin products described in this section that are delivered by an out-of-network provider, or precludes a plan or issuer that has

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

''(d) RULE OF CONSTRUCTION.—Subsection (a) shall not be construed to require coverage of, or prevent a group health plan or health insurance coverage from imposing cost-sharing other than the levels specified in subsection (a) on, insulin products that are not selected insulin products, to the extent that such coverage is not otherwise required and such cost-sharing is otherwise permitted under Federal and applicable State law.

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

(b) IRC.—

(1) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

''SEC. 9826. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

''(a) IN GENERAL.—For plan years beginning on or after January 1, 2023, a group health plan shall provide

coverage of selected insulin products and, with respect to such products, shall not—

''(1) apply any deductible; or

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

''(A) $35; or

''(B) the amount equal to 25 percent of the negotiated price of the selected insulin product net of all price concessions received by or on behalf of the plan, including price concessions received by or on behalf of third-party entities providing services to the plan, such as pharmacy benefit management services.

''(b) DEFINITIONS.—In this section:

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

''(2) INSULIN DEFINED.—The term 'insulin' means insulin that is licensed under subsection (a) or (k) of section 351 of the Public Health Service

Act and continues to be marketed under such section, including any insulin product that has been deemed to be licensed under section 351(a) of such Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 and continues to be marketed pursuant to such licensure.

''(c) OUT-OF-NETWORK PROVIDERS.—Nothing in this section requires a plan that has a network of providers to provide benefits for selected insulin products described in this section that are delivered by an out-of-network provider, or precludes a plan that has a network of providers from imposing higher cost-sharing than the levels specified in subsection (a) for selected insulin products described in this section that are delivered by an out-of-network provider.

''(d) RULE OF CONSTRUCTION.—Subsection (a) shall not be construed to require coverage of, or prevent a group health plan from imposing cost-sharing other than the levels specified in subsection (a) on, insulin products that are not selected insulin products, to the extent that such coverage is not otherwise required and such cost-sharing is otherwise permitted under Federal and applicable State law.

''(e) APPLICATION OF COST-SHARING TOWARDS DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any

cost-sharing payments made pursuant to subsection (a)(2) shall be counted toward any deductible or out-of-pocket maximum that applies under the plan.''.

(2) CLERICAL AMENDMENT.—The table of sections for subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

''Sec. 9826. Requirements with respect to cost-sharing for certain insulin products.''.

(c) ERISA.—

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

''SEC. 726. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

''(a) IN GENERAL.—For plan years beginning on or after January 1, 2023, a group health plan or health insurance issuer offering group health insurance coverage shall provide coverage of selected insulin products and, with respect to such products, shall not—

''(1) apply any deductible; or

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

''(A) $35; or

''(B) the amount equal to 25 percent of the negotiated price of the selected insulin product net of all price concessions received by or on behalf of the plan or coverage, including price concessions received by or on behalf of third-party entities providing services to the plan or coverage, such as pharmacy benefit management services.

''(b) DEFINITIONS.—In this section:

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

''(2) INSULIN DEFINED.—The term 'insulin' means insulin that is licensed under subsection (a) or (k) of section 351 of the Public Health Service Act and continues to be marketed under such section, including any insulin product that has been deemed to be licensed under section 351(a) of such Act pursuant to section 7002(e)(4) of the Biologics

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

''(c) OUT-OF-NETWORK PROVIDERS.—Nothing in this section requires a plan or issuer that has a network of providers to provide benefits for selected insulin products described in this section that are delivered by an out-of-network provider, or precludes a plan or issuer that has a network of providers from imposing higher cost-sharing than the levels specified in subsection (a) for selected insulin products described in this section that are delivered by an out-of-network provider.

''(d) RULE OF CONSTRUCTION.—Subsection (a) shall not be construed to require coverage of, or prevent a group health plan or health insurance coverage from imposing cost-sharing other than the levels specified in subsection (a) on, insulin products that are not selected insulin products, to the extent that such coverage is not otherwise required and such cost-sharing is otherwise permitted under Federal and applicable State law.

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

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.) is amended by inserting after the item relating to section 725 the following:

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

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

"(D) SPECIAL RULE RELATING TO INSULIN COVERAGE.—The exemption of coverage of selected insulin products (as defined in section 2799A–11(b) of the Public Health Service Act) from the application of any deductible pursuant to section 2799A–11(a)(1) of such Act, section 726(a)(1) of the Employee Retirement Income Security Act of 1974, or section 9826(a)(1) of the Internal Revenue Code of 1986 shall not be considered when determining the actuarial value of a qualified health plan under this subsection.".

(e) COVERAGE OF CERTAIN INSULIN PRODUCTS UNDER CATASTROPHIC PLANS.—Section 1302(e) of the

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

"(4) COVERAGE OF CERTAIN INSULIN PRODUCTS.—

"(A) IN GENERAL.—Notwithstanding paragraph (1)(B)(i), a health plan described in paragraph (1) shall provide coverage of selected insulin products, in accordance with section 2799A–11 of the Public Health Service Act, before an enrolled individual has incurred, during a plan year, cost-sharing expenses in an amount equal to the annual limitation in effect under subsection (c)(1) for the plan year.

"(B) TERMINOLOGY.—For purposes of subparagraph (A)—

"(i) the term 'selected insulin products' has the meaning given such term in section 2799A–11(b) of the Public Health Service Act; and

"(ii) the requirements of section 2799A–11 of such Act shall be applied by deeming each reference in such section to 'individual health insurance coverage' to be a reference to a plan described in paragraph (1).".

(f) IMPLEMENTATION.—The Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury may implement the provisions of, including the amendments made by, this section through sub-regulatory guidance, program instruction, or otherwise.

SEC. 3. APPROPRIATE COST-SHARING FOR CERTAIN INSULIN PRODUCTS UNDER MEDICARE PART D.

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

(1) in subsection (b)—

(A) in paragraph (1)(A), by striking ''The coverage'' and inserting ''Subject to paragraph (8), the coverage'';

(B) in paragraph (2)—

(i) in subparagraph (A), by striking ''and (D)'' and inserting ''and (D) and paragraph (8)'';

(ii) in subparagraph (B), by striking ''and (D)'' and inserting ''and (D) and paragraph (8)'';

(iii) in subparagraph (C)(i), by striking ''paragraph (4)'' and inserting ''paragraphs (4) and (8)''; and

(iv) in subparagraph (D)(i), by striking ''paragraph (4)'' and inserting ''paragraphs (4) and (8)'';

(C) in paragraph (3)(A), by striking ''and (4)'' and inserting ''(4), and (8)'';

(D) in paragraph (4)(A)(i), by striking ''The coverage'' and inserting ''Subject to paragraph (8), the coverage''; and

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

''(8) TREATMENT OF COST-SHARING FOR CERTAIN INSULIN PRODUCTS.—

''(A) IN GENERAL.—For plan years beginning on or after January 1, 2023, with respect to an individual, the following shall apply with respect to any insulin product (as defined in subparagraph (B)) that is covered under the prescription drug plan or MA–PD plan in which the individual is enrolled:

''(i) NO APPLICATION OF DEDUCTIBLE.—The deductible under paragraph (1) shall not apply with respect to such insulin product.

''(ii) APPLICATION OF COST-SHARING.—

''(I) IN GENERAL.—The coverage provides benefits for such insulin product, regardless of whether an individual has reached the initial coverage limit under paragraph (3) or the out-of-pocket threshold under paragraph (4), with cost-sharing for a one-month supply that is equal to the applicable copayment amount.

''(II) APPLICABLE COPAYMENT AMOUNT.—For purposes of this clause, the term 'applicable copayment amount' means, with respect to an insulin product under a prescription drug plan or an MA–PD plan, an amount that is not more than $35.

''(B) INSULIN PRODUCT.—For purposes of this paragraph, the term 'insulin product' means a covered part D drug that is an insulin product that is approved under section 505 of the Federal Food, Drug, and Cosmetic Act or licensed under section 351 of the Public Health Service Act and marketed pursuant to such approval or licensure, including any insulin product that has been deemed to be licensed under

section 351 of the Public Health Service Act pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 and marketed pursuant to such section.''; and

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

''(4) TREATMENT OF COST-SHARING FOR INSULIN PRODUCTS.—The coverage is provided in accordance with subsection (b)(8).''.

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

(1) in paragraph (1)—

(A) in subparagraph (D)(iii), by adding at the end the following new sentence: ''For plan year 2023 and subsequent plan years, the copayment amount applicable under the preceding sentence for a one-month supply of an insulin product (as defined in subparagraph (B) of section 1860D–2(b)(8)) dispensed to the individual may not exceed the applicable copayment amount (as defined in subparagraph (A)(ii)(II) of such section) for the product under the pre-

scription drug plan or MA–PD plan in which the individual is enrolled.''; and

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

(2) in paragraph (2)—

(A) in subparagraph (B), by adding at the end the following new sentence: ''For plan year 2023 and subsequent plan years, the annual deductible applicable under such section, including as reduced under the preceding sentence, shall not apply with respect to an insulin product (as defined in subparagraph (B) of section 1860D–2(b)(8)) dispensed to the individual.'';

(B) in subparagraph (D), by adding at the end the following new sentence: ''For plan year 2023 and subsequent plan years, the amount of the coinsurance applicable under the preceding sentence for a one-month supply of an insulin product (as defined in subparagraph (B) of section 1860D–2(b)(8)) dispensed to the individual may not exceed the applicable copayment amount (as defined in subparagraph (A)(ii)(II)

of such section) for the product under the prescription drug plan or MA–PD plan in which the individual is enrolled.''; and

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

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

SEC. 4. ONE YEAR-EXTENSION ON MORATORIUM ON IMPLEMENTATION OF RULE RELATING TO ELIMINATING THE ANTI-KICKBACK STATUTE SAFE HARBOR PROTECTION FOR PRESCRIPTION DRUG REBATES.

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

SEC. 5. MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1) of the Social Security Act (42 U.S.C. 1395iii(b)(1)), as amended by section 313 of division P of the Consolidated Appropriations Act, 2022, is amended by striking ''$5,000,000'' and inserting ''$9,046,500,000''.

Passed the House of Representatives March 31, 2022.

Attest:

Clerk.

117TH CONGRESS
2D 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.