

MARCH 28, 2022

RULES COMMITTEE PRINT 117–38
TEXT OF H.R. 6833, THE AFFORDABLE INSULIN
NOW ACT

[Showing the text of H.R. 6833, as introduced, with
modifications.]

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—

1 “(A) \$35; or

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

10 “(b) DEFINITIONS.—In this section:

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

19 “(2) INSULIN DEFINED.—The term ‘insulin’
20 means insulin that is licensed under subsection (a)
21 or (k) of section 351 and continues to be marketed
22 under such section, including any insulin product
23 that has been deemed to be licensed under section
24 351(a) pursuant to section 7002(e)(4) of the Bio-
25 logics Price Competition and Innovation Act of 2009

1 and continues to be marketed pursuant to such li-
2 censure.

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.”.

25 (b) IRC.—

1 (1) IN GENERAL.—Subchapter B of chapter
2 100 of the Internal Revenue Code of 1986 is amend-
3 ed by adding at the end the following new section:

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

6 “(a) IN GENERAL.—For plan years beginning on or
7 after January 1, 2023, a group health plan shall provide
8 coverage of selected insulin products and, with respect to
9 such products, shall not—

10 “(1) apply any deductible; or

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

13 “(A) \$35; or

14 “(B) the amount equal to 25 percent of
15 the negotiated price of the selected insulin prod-
16 uct net of all price concessions received by or on
17 behalf of the plan, including price concessions
18 received by or on behalf of third-party entities
19 providing services to the plan, such as phar-
20 macy benefit management services.

21 “(b) DEFINITIONS.—In this section:

22 “(1) SELECTED INSULIN PRODUCTS.—The term
23 ‘selected insulin products’ means at least one of each
24 dosage form (such as vial, pump, or inhaler dosage
25 forms) of each different type (such as rapid-acting,

1 short-acting, intermediate-acting, long-acting, ultra
2 long-acting, and premixed) of insulin (as defined
3 below), when available, as selected by the group
4 health plan.

5 “(2) INSULIN DEFINED.—The term ‘insulin’
6 means insulin that is licensed under subsection (a)
7 or (k) of section 351 of the Public Health Service
8 Act and continues to be marketed under such sec-
9 tion, including any insulin product that has been
10 deemed to be licensed under section 351(a) of such
11 Act pursuant to section 7002(e)(4) of the Biologics
12 Price Competition and Innovation Act of 2009 and
13 continues to be marketed pursuant to such licensure.

14 “(c) OUT-OF-NETWORK PROVIDERS.—Nothing in
15 this section requires a plan that has a network of providers
16 to provide benefits for selected insulin products described
17 in this section that are delivered by an out-of-network pro-
18 vider, or precludes a plan that has a network of providers
19 from imposing higher cost-sharing than the levels specified
20 in subsection (a) for selected insulin products described
21 in this section that are delivered by an out-of-network pro-
22 vider.

23 “(d) RULE OF CONSTRUCTION.—Subsection (a) shall
24 not be construed to require coverage of, or prevent a group
25 health plan from imposing cost-sharing other than the lev-

1 els specified in subsection (a) on, insulin products that are
2 not selected insulin products, to the extent that such cov-
3 erage is not otherwise required and such cost-sharing is
4 otherwise permitted under Federal and applicable State
5 law.

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

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

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

15 (c) ERISA.—

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

20 **“SEC. 726. 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 or health in-
24 surance issuer offering group health insurance coverage

1 shall provide coverage of selected insulin products and,
2 with respect to 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 or coverage, including price
11 concessions received by or on behalf of third-
12 party entities providing services to the plan or
13 coverage, such as pharmacy benefit manage-
14 ment services.

15 “(b) DEFINITIONS.—In this section:

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

24 “(2) INSULIN DEFINED.—The term ‘insulin’
25 means insulin that is licensed under subsection (a)

1 or (k) of section 351 of the Public Health Service
2 Act and continues to be marketed under such sec-
3 tion, including any insulin product that has been
4 deemed to be licensed under section 351(a) of such
5 Act pursuant to section 7002(e)(4) of the Biologics
6 Price Competition and Innovation Act of 2009 and
7 continues to be marketed pursuant to such licensure.

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

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

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

6 (2) CLERICAL AMENDMENT.—The table of con-
7 tents in section 1 of the Employee Retirement In-
8 come Security Act of 1974 (29 U.S.C. 1001 et seq.)
9 is amended by inserting after the item relating to
10 section 725 the following:

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

11 (d) NO EFFECT ON OTHER COST-SHARING.—Section
12 1302(d)(2) of the Patient Protection and Affordable Care
13 Act (42 U.S.C. 18022(d)(2)) is amended by adding at the
14 end the following new subparagraph:

15 “(D) SPECIAL RULE RELATING TO INSU-
16 LIN COVERAGE.—The exemption of coverage of
17 selected insulin products (as defined in section
18 2799A–11(b) of the Public Health Service Act)
19 from the application of any deductible pursuant
20 to section 2799A–11(a)(1) of such Act, section
21 726(a)(1) of the Employee Retirement Income
22 Security Act of 1974, or section 9826(a)(1) of
23 the Internal Revenue Code of 1986 shall not be
24 considered when determining the actuarial value

1 of a qualified health plan under this sub-
2 section.”.

3 (e) COVERAGE OF CERTAIN INSULIN PRODUCTS
4 UNDER CATASTROPHIC PLANS.—Section 1302(e) of the
5 Patient Protection and Affordable Care Act (42 U.S.C.
6 18022(e)) is amended by adding at the end the following:

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

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

18 “(B) TERMINOLOGY.—For purposes of
19 subparagraph (A)—

20 “(i) the term ‘selected insulin prod-
21 ucts’ has the meaning given such term in
22 section 2799A–11(b) of the Public Health
23 Service Act; and

24 “(ii) the requirements of section
25 2799A–11 of such Act shall be applied by

1 deeming each reference in such section to
2 ‘individual health insurance coverage’ to be
3 a reference to a plan described in para-
4 graph (1).”.

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

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

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

15 (1) in subsection (b)—

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

19 (B) in paragraph (2)—

20 (i) in subparagraph (A), by striking
21 “and (D)” and inserting “and (D) and
22 paragraph (8)”;

23 (ii) in subparagraph (B), by striking
24 “and (D)” and inserting “and (D) and
25 paragraph (8)”;

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

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

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

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

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

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

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

23 “(i) NO APPLICATION OF DEDUCT-
24 IBLE.—The deductible under paragraph

1 (1) shall not apply with respect to such in-
2 sulin product.

3 “(ii) APPLICATION OF COST-SHAR-
4 ING.—

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

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

21 “(B) INSULIN PRODUCT.—For purposes of
22 this paragraph, the term ‘insulin product’
23 means a covered part D drug that is an insulin
24 product that is approved under section 505 of
25 the Federal Food, Drug, and Cosmetic Act or

1 licensed under section 351 of the Public Health
2 Service Act and marketed pursuant to such ap-
3 proval or licensure, including any insulin prod-
4 uct that has been deemed to be licensed under
5 section 351 of the Public Health Service Act
6 pursuant to section 7002(e)(4) of the Biologics
7 Price Competition and Innovation Act of 2009
8 and marketed pursuant to such section.”; and
9 (2) in subsection (c), by adding at the end the
10 following new paragraph:

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

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

18 (1) in paragraph (1)—

19 (A) in subparagraph (D)(iii), by adding at
20 the end the following new sentence: “For plan
21 year 2023 and subsequent plan years, the co-
22 payment amount applicable under the preceding
23 sentence for a one-month supply of an insulin
24 product (as defined in subparagraph (B) of sec-
25 tion 1860D–2(b)(8)) dispensed to the individual

1 may not exceed the applicable copayment
2 amount (as defined in subparagraph (A)(ii)(II)
3 of such section) for the product under the pre-
4 scription drug plan or MA–PD plan in which
5 the individual is enrolled.”; and

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

11 (2) in paragraph (2)—

12 (A) in subparagraph (B), by adding at the
13 end the following new sentence: “For plan year
14 2023 and subsequent plan years, the annual de-
15 ductible applicable under such section, including
16 as reduced under the preceding sentence, shall
17 not apply with respect to an insulin product (as
18 defined in subparagraph (B) of section 1860D–
19 2(b)(8)) dispensed to the individual.”;

20 (B) in subparagraph (D), by adding at the
21 end the following new sentence: “For plan year
22 2023 and subsequent plan years, the amount of
23 the coinsurance applicable under the preceding
24 sentence for a one-month supply of an insulin
25 product (as defined in subparagraph (B) of sec-

1 tion 1860D–2(b)(8)) dispensed to the individual
2 may not exceed the applicable copayment
3 amount (as defined in subparagraph (A)(ii)(II)
4 of such section) for the product under the pre-
5 scription drug plan or MA–PD plan in which
6 the individual is enrolled.”; and

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

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

23 (d) FUNDING.—In addition to amounts otherwise
24 available, there is appropriated to the Centers for Medi-
25 care & Medicaid Services, out of any money in the Treas-

1 ury not otherwise appropriated, \$1,500,000 for fiscal year
2 2022, to remain available until expended, to carry out the
3 provisions of, including the amendments made by, this sec-
4 tion.

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

10 Section 90006 of the Infrastructure Investment and
11 Jobs Act (P.L. 117–58) is amended by striking “January
12 1, 2026” and inserting “January 1, 2027”.

13 **SEC. 5. MEDICARE IMPROVEMENT FUND.**

14 Section 1898(b)(1) of the Social Security Act (42
15 U.S.C. 1395iii(b)(1)), as amended by section 313 of divi-
16 sion P of the Consolidated Appropriations Act, 2022, is
17 amended by striking “\$5,000,000” and inserting
18 “\$9,046,500,000”.

