To provide for appropriate cost-sharing for insulin products covered under Medicare part D and private health plans.

IN THE SENATE OF THE UNITED STATES

Mr. Warnock (for himself, Mr. Schumer, Mr. Durbin, Mr. Wyden, Mr. Bennet, Mr. Blumenthal, Ms. Baldwin, Mr. Kelly, Ms. Stabenow, Mr. Reed, Mr. Van Hollen, Ms. Hirono, Ms. Klobuchar, Mr. Murphy, Ms. Hassan, Mrs. Shaheen, Mr. Booker, Mr. King, Ms. Smith, and Mr. Padilla) introduced the following bill; which was read twice and referred to the Committee on

A BILL

To provide for appropriate cost-sharing for insulin products covered under Medicare part D and private health plans.

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. APPROPRIATE COST-SHARING FOR INSULIN PRODUCTS COVERED UNDER MEDICARE PART D AND PRIVATE HEALTH PLANS.

(a) Medicare Part D.—

(1) In general.—Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102) is amended—

(A) in subsection (b)—

(i) in paragraph (1)(A), in the matter preceding clause (i), by striking “The coverage” and inserting “Subject to paragraph (8), the coverage”;

(ii) in paragraph (2)—

(I) in subparagraph (A), in the matter preceding clause (i), by striking “and (D)” and inserting “and (D) and paragraph (8)”;

(II) in subparagraph (C)(i), in the matter preceding subclause (I), by striking “paragraph (4)” and inserting “paragraphs (4) and (8)”;

(III) in subparagraph (D)(i), in the matter preceding subclause (I), by striking “paragraph (4)” and inserting “paragraphs (4) and (8)”;

(ii) in paragraph (3)—

(I) in clause (iv)(I), by striking “the coverage” and inserting “Coverage under paragraph (8)”;

(two other paragraphs are amended in a similar manner.)
(iii) in paragraph (3)(A), in the matter preceding clause (i), by striking “and (4)” and inserting “(4), and (8)”;

(iv) in paragraph (4)(A)(i), in the matter preceding subclause (I), by striking “The coverage” and inserting “Subject to paragraph (8), the coverage”; and

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

“(8) TREATMENT OF COST-SHARING FOR COVERED INSULIN PRODUCTS.—

“(A) IN GENERAL.—For the portion of plan year 2022 beginning on October 1, 2022, and ending on December 31, 2022, and for plan year 2023 and subsequent plan years, the following rules shall apply with respect to cost-sharing for a month’s supply of any covered insulin product (as defined in subparagraph (B)) that is covered under the prescription drug plan or MA-PD plan:

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

“(ii) MAXIMUM COST-SHARING.—
“(I) IN GENERAL.—The coverage shall provide benefits for such any covered insulin product, regardless of whether an individual has reached the initial coverage limit under paragraph (3) or the annual out-of-pocket threshold under paragraph (4), with cost-sharing for a month’s supply that does not exceed the maximum cost-sharing amount.

“(II) MAXIMUM COST-SHARING AMOUNT.—For purposes of subclause (I), the term ‘maximum cost-sharing amount’ means, with respect to a covered insulin product under a prescription drug plan or an MA–PD plan dispensed—

“(aa) on or after October 1, 2022, and before January 1, 2024, $35; and

“(bb) during plan year 2024 or subsequent plan year, the lesser of—

“(AA) $35; or
“(BB) an amount equal to 25 percent of the negotiated price of the covered insulin product under the prescription drug plan or MA–PD plan.

“(B) COVERED INSULIN PRODUCT.—For purposes of this paragraph, the term ‘covered 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 continues to be marketed, 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 continues to be marketed.”; and

(B) 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).”.
(2) 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—

(A) in paragraph (1)—

(i) in subparagraph (D)(iii), by adding at the end the following new sentence:

“For the portion of plan year 2022 beginning on October 1, 2022, and ending on December 31, 2022, and for plan year 2023 and subsequent plan years, the copayment amount applicable under the preceding sentence to a month’s supply of a covered insulin product (as described in section 1860D–2(b)(8)) dispensed to the individual may not exceed the applicable copayment or coinsurance amount for the product under the prescription drug plan or MA–PD plan in which the individual is enrolled.”; and

(ii) in subparagraph (E), by inserting the following before the period at the end:

“or under section 1860D–2(b)(8) in the case of a covered insulin product (as described in such section)”;

and
(B) in paragraph (2)—

(i) in subparagraph (D), by adding at the end the following new sentence: “For the portion of plan year 2022 beginning on October 1, 2022, and ending on December 31, 2022, and for plan year 2023 and subsequent plan years, the amount of the coinsurance applicable under the preceding sentence to a month’s supply of a covered insulin product (as described in section 1860D–2(b)(8)) dispensed to the individual may not exceed the applicable copayment or coinsurance amount for the product under the prescription drug plan or MA–PD plan in which the individual is enrolled.”; and

(ii) in subparagraph (E), by adding at the end the following new sentence: “For the portion of plan year 2022 beginning on October 1, 2022, and ending on December 31, 2022, and for plan year 2023 and subsequent plan years, the amount of the copayment or coinsurance applicable under the preceding sentence to a month’s supply of a covered insulin product (as described
in section 1860D–2(b)(8)) dispensed to the individual may not exceed the applicable copayment or coinsurance amount for the product under the prescription drug plan or MA–PD plan in which the individual is enrolled.”.

(3) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary of Health and Human Services may implement the provisions of, including the amendments made by, this subsection for plan years 2022, 2023, and 2024 by program instruction or otherwise.

(4) FUNDING.—In addition to amounts otherwise available, there is appropriated to the Centers for Medicare & Medicaid Services, out of any money in the Treasury not otherwise appropriated, $1,500,000 for fiscal year 2022, to remain available until expended, to carry out the provisions of, including the amendments made by, this subsection.

(b) PRIVATE HEALTH PLANS.—

(1) IN GENERAL.—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:
"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 Bio-
logics Price Competition and Innovation Act of 2009
and continues to be marketed pursuant to such li-
censure.

“(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 prod-
ucts 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 insu-
lin 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 prod-
uents, to the extent that such coverage is not otherwise re-
quired 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) No Effect on Other Cost-sharing.—
Section 1302(d)(2) of the Patient Protection and Af-
fordable 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 insu-
lin 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 sub-
section.”.
(3) 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 the plan year, cost-sharing expenses in an amount equal to the annual limitation in effect under subsection (e)(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).”.

(4) ERISA.—

(A) 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 manage-
ment services.

“(b) DEFINITIONS.—In this section:

“(1) SELECTED INSULIN PRODUCTS.—The term
’slected 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 (42 U.S.C. 262) 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(c)(4)
of the Biologics Price Competition and Innovation
Act of 2009 (Public Law 111–148) 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 prod-
ucts 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 insu-
lin 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 prod-
ucts, to the extent that such coverage is not otherwise re-
quired 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) Clerical Amendment.—The table of
contents in section 1 of the Employee Retire-
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 prod-
ucts.”.
(5) **INTERNAL REVENUE CODE.** —

**(A) 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:

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“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
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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 (42 U.S.C. 262) 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 (Public Law 111–148) 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.”.

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

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

(6) 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 subsection through sub-regulatory guidance, program instruction or otherwise.