118th CONGRESS 1st Session **S**.

To provide for appropriate cost-sharing for insulin products covered under private health plans, and to establish a program to support health care providers and pharmacies in providing discounted insulin products to uninsured individuals.

IN THE SENATE OF THE UNITED STATES

Mr. WARNOCK (for himself and Mr. KENNEDY) 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 private health plans, and to establish a program to support health care providers and pharmacies in providing discounted insulin products to uninsured individuals.
 - 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 of 2023".

1	SEC. 2. APPROPRIATE COST-SHARING FOR INSULIN PROD-				
2	UCTS COVERED UNDER PRIVATE HEALTH				
3	PLANS.				
4	(a) IN GENERAL.—Part D of title XXVII of the Pub-				
5	lic Health Service Act (42 U.S.C. 300gg–111 et seq.) is				
6	amended by adding at the end the following:				
7	"SEC. 2799A-11. REQUIREMENTS WITH RESPECT TO COST-				
8	SHARING FOR CERTAIN INSULIN PRODUCTS.				
9	"(a) IN GENERAL.—For plan years beginning on or				
10	after January 1, 2024, a group health plan or health in-				
11	surance issuer offering group or individual health insur-				
12	ance coverage shall provide coverage of selected insulin				
13	products, and with respect to such products, shall not—				
14	"(1) apply any deductible; or				
15	((2) impose any cost-sharing in excess of the				
16	lesser of, per 30-day supply—				
17	"(A) \$35; or				
18	"(B) the amount equal to 25 percent of				
19	the negotiated price of the selected insulin prod-				
20	uct net of all price concessions received by or on				
21	behalf of the plan or coverage, including price				
22	concessions received by or on behalf of third-				
23	party entities providing services to the plan or				
24	coverage, such as pharmacy benefit manage-				
25	ment services.				
26	"(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.

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

TAM23338 1ST

4

(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.

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

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

14 "(D) SPECIAL RULE RELATING TO INSU-15 LIN COVERAGE.—The exemption of coverage of 16 selected insulin products (as defined in section 17 2799A–11(b) of the Public Health Service Act) 18 from the application of any deductible pursuant 19 to section 2799A-11(a)(1) of such Act, section 20 726(a)(1) of the Employee Retirement Income 21 Security Act of 1974, or section 9826(a)(1) of 22 the Internal Revenue Code of 1986 shall not be 23 considered when determining the actuarial value 24 of a qualified health plan under this sub-25 section.".

1 (c) COVERAGE OF CERTAIN INSULIN PRODUCTS 2 UNDER CATASTROPHIC PLANS.—Section 1302(e) of the 3 Patient Protection and Affordable Care Act (42 U.S.C. 4 18022(e)) is amended by adding at the end the following: 5 "(4) COVERAGE OF CERTAIN INSULIN PROD-6 UCTS.— "(A) IN GENERAL.—Notwithstanding para-7 8 graph (1)(B)(i), a health plan described in 9 paragraph (1) shall provide coverage of selected 10 insulin products, in accordance with section 11 2799A–11 of the Public Health Service Act, be-12 fore an enrolled individual has incurred, during 13 the plan year, cost-sharing expenses in an 14 amount equal to the annual limitation in effect 15 under subsection (c)(1) for the plan year. TERMINOLOGY.—For purposes of 16 "(B) 17 subparagraph (A)— 18 "(i) the term 'selected insulin prod-19 ucts' has the meaning given such term in 20 section 2799A–11(b) of the Public Health 21 Service Act; and 22 "(ii) the requirements of section 23 2799A–11 of such Act shall be applied by 24 deeming each reference in such section to 25 'individual health insurance coverage' to be

TAM23338 1ST

S.L.C.

6

1	a reference to a plan described in para-
2	graph (1).".
3	(d) ERISA.—
4	(1) IN GENERAL.—Subpart B of part 7 of sub-
5	title B of title I of the Employee Retirement Income
6	Security Act of 1974 (29 U.S.C. 1185 et seq.) is
7	amended by adding at the end the following:
8	"SEC. 726. REQUIREMENTS WITH RESPECT TO COST-SHAR-
9	ING FOR CERTAIN INSULIN PRODUCTS.
10	"(a) IN GENERAL.—For plan years beginning on or
11	after January 1, 2024, a group health plan or health in-
12	surance issuer offering group health insurance coverage
13	shall provide coverage of selected insulin products, and
14	with respect to such products, shall not—
15	"(1) apply any deductible; or
16	((2) impose any cost-sharing in excess of the
17	lesser of, per 30-day supply—
18	"(A) \$35; or
19	"(B) the amount equal to 25 percent of
20	the negotiated price of the selected insulin prod-
21	uct net of all price concessions received by or on
22	behalf of the plan or coverage, including price
23	concessions received by or on behalf of third-
24	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 forms) of each different type (such as rapid-acting, 7 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.

"(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.

17 "(c) OUT-OF-NETWORK PROVIDERS.—Nothing in 18 this section requires a plan or issuer that has a network 19 of providers to provide benefits for selected insulin prod-20 ucts described in this section that are delivered by an out-21 of-network provider, or precludes a plan or issuer that has 22 a network of providers from imposing higher cost-sharing 23 than the levels specified in subsection (a) for selected insu-24 lin products described in this section that are delivered 25 by an out-of-network provider.

TAM23338 1ST

8

1 "(d) RULE OF CONSTRUCTION.—Subsection (a) shall not be construed to require coverage of, or prevent a group 2 3 health plan or health insurance coverage from imposing cost-sharing other than the levels specified in subsection 4 5 (a) on, insulin products that are not selected insulin products, to the extent that such coverage is not otherwise re-6 7 quired and such cost-sharing is otherwise permitted under 8 Federal and applicable State law.

9 "(e) APPLICATION OF COST-SHARING TOWARDS 10 DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any 11 cost-sharing payments made pursuant to subsection (a)(2) 12 shall be counted toward any deductible or out-of-pocket 13 maximum that applies under the plan or coverage.".

14 (2) CLERICAL AMENDMENT.—The table of con15 tents in section 1 of the Employee Retirement In16 come Security Act of 1974 (29 U.S.C. 1001 et seq.)
17 is amended by inserting after the item relating to
18 section 725 the following:

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

- 19 (e) INTERNAL REVENUE CODE.—
- 20 (1) IN GENERAL.—Subchapter B of chapter
 21 100 of the Internal Revenue Code of 1986 is amend22 ed by adding at the end the following new section:

1	"SEC. 9826. REQUIREMENTS WITH RESPECT TO COST-SHAR-
2	ING FOR CERTAIN INSULIN PRODUCTS.
3	"(a) IN GENERAL.—For plan years beginning on or
4	after January 1, 2024, a group health plan shall provide
5	coverage of selected insulin products, and with respect to
6	such products, shall not—
7	"(1) apply any deductible; or
8	((2) impose any cost-sharing in excess of the
9	lesser of, per 30-day supply—
10	"(A) \$35; or
11	"(B) the amount equal to 25 percent of
12	the negotiated price of the selected insulin prod-
13	uct net of all price concessions received by or on
14	behalf of the plan, including price concessions
15	received by or on behalf of third-party entities
16	providing services to the plan, such as phar-
17	macy benefit management services.
18	"(b) DEFINITIONS.—In this section:
19	"(1) Selected insulin products.—The term
20	'selected insulin products' means at least one of each
21	dosage form (such as vial, pump, or inhaler dosage
22	forms) of each different type (such as rapid-acting,
23	short-acting, intermediate-acting, long-acting, ultra
24	long-acting, and premixed) of insulin (as defined
25	below), when available, as selected by the group
26	health plan.

S.L.C.

10

"(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.

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 from imposing higher cost-sharing than the levels specified 11 12 in subsection (a) for selected insulin products described 13 in this section that are delivered by an out-of-network provider. 14

15 "(d) RULE OF CONSTRUCTION.—Subsection (a) shall not be construed to require coverage of, or prevent a group 16 health plan from imposing cost-sharing other than the lev-17 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)

shall be counted toward any deductible or out-of-pocket
 maximum that applies under the plan.".

3 (2) CLERICAL AMENDMENT.—The table of sec4 tions for subchapter B of chapter 100 of such Code
5 is amended by adding at the end the following new
6 item:

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

7 (f) IMPLEMENTATION.—The Secretary of Health and 8 Human Services, the Secretary of Labor, and the Sec-9 retary of the Treasury may implement the provisions of, 10 including the amendments made by, this subsection 11 through sub-regulatory guidance, program instruction or 12 otherwise.

13 SEC. 3. REIMBURSEMENT FOR INSULIN FURNISHED TO UN14 INSURED INDIVIDUALS.

(a) IN GENERAL.—The Secretary of Health and
Human Services (in this section referred to as the "Secretary") shall establish a program under which the Secretary enters into agreements with qualifying entities for
purposes of furnishing insulin products to uninsured individuals.

(b) PAYMENT.—The Secretary shall pay to each
qualifying entity with an agreement in effect under this
section, with respect to each 30-day supply of insulin products furnished to an uninsured individual by such entity

on or after January 1, 2024, an amount equal to the dif-1 2 ference between the out-of-pocket cost to the individual for 3 a 30-day supply of such insulin products and \$35. 4 (c) DEFINITIONS.—In this section: (1) INSULIN PRODUCT.—The term "insulin 5 6 product" has the meaning given the term "insulin" 7 in section 2799A–11 of the Public Health Service 8 Act, as added by section 2. 9 (2) QUALIFYING ENTITY.—The term "qualifying entity" means a health care provider or phar-10 11 macy that— 12 (A) agrees, with respect to an insulin prod-13 uct furnished by such provider or pharmacy to 14 an uninsured individual after January 1, 2024, 15 for which payment is made by the Secretary 16 under this section, not to hold such individual 17 liable for any payment amount for such prod-18 uct; and 19 (B) meets such other standards and re-20 quirements as may be determined appropriate 21 by the Secretary. 22 Specified HEALTH PLAN.—The (3)term 23 "specified health plan" means a Federal health care 24 program (as defined in section 1128B of the Social 25 Security Act (42 U.S.C. 1320a–7b)), the health pro-

gram established under chapter 89 of title 5, United
 States Code, a group health plan (as defined in sec tion 2791 of the Public Health Service Act (42
 U.S.C. 300gg-91), and group or individual health
 insurance coverage (as defined in such section
 2791).

7 (4) UNINSURED INDIVIDUAL.—The term "uninsured individual" means, with respect to an indi-8 9 vidual and an insulin product, an individual who 10 does not have benefits available for such product (or 11 for another insulin product of the same dosage form 12 (such as vial, pump, or inhaler dosage forms) and 13 type (such as rapid-acting, short-acting, inter-14 mediate-acting, long-acting, ultra-long-acting, and 15 premixed)) under a specified health plan.

16 SEC. 4. SENSE OF CONGRESS.

17 It is the sense of Congress that subsequent legislation
18 should be enacted by Congress that provides for an offset
19 for any costs to the Federal Government resulting from
20 the enactment of this Act.