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(Original Signature of Member)

119TH CONGRESS
2D SESSION

H. R. _____

To reduce the price of insulin and provide for patient protections with respect to the cost of insulin.

IN THE HOUSE OF REPRESENTATIVES

Ms. DEGETTE introduced the following bill; which was referred to the Committee on _____

A BILL

To reduce the price of insulin and provide for patient protections with respect to the cost of insulin.

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 ''Improving Needed Safeguards for Users of Lifesaving Insulin Now Act of 2026'' or the ''INSULIN Act of 2026''.

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

(a) IN GENERAL.—Subpart II of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–11 et seq.) is amended by adding at the end the following:

"SEC. 2729A. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

''(a) IN GENERAL.—For plan years beginning on or after January 1, 2028, 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 requirements in excess of, per 30-day supply—

''(A) for any applicable plan year beginning before January 1, 2028, $35; or

''(B) for any plan year beginning on or after January 1, 2028, the lesser of—

''(i) $35; or

''(ii) 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 issuer, including price concessions received by or

on behalf of third-party entities providing services to the plan or issuer, such as pharmacy benefit management services or third party administrators.

''(b) DEFINITIONS.—In this section:

''(1) SELECTED INSULIN PRODUCTS.—The term 'selected insulin products' means, for any plan year beginning on or after January 1, 2028, at least one of each dosage form and delivery device (such as vial, pen, inhaler dosage forms, or such other delivery devices approved by the Secretary) of each different type (such as rapid-acting, short-acting, intermediate-acting, long-acting, and pre-mixed) of insulin, when such form is licensed and marketed, as selected by the group health plan or health insurance issuer.

''(2) INSULIN.—The term 'insulin' means insulin that is licensed under subsection (a) or (k) of section 351, including insulin deemed to be licensed under section 351 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 if permitted under applicable law.

''(d) RULES OF CONSTRUCTION.—Subsection (a) shall not be construed to—

''(1) require coverage of, or prevent a group health plan or health insurance issuer from imposing cost-sharing other than the levels specified in subsection (a) on, insulin that is not a selected insulin product, to the extent that such coverage is not otherwise required and such cost-sharing is otherwise permitted under Federal and applicable State law; or

''(2) permit a group health plan or health insurance issuer to pay any amount in excess of the amount specified under section (a)(2) to an entity providing pharmaceutical benefit management services, a provider, or a pharmaceutical manufacturer with respect to the provision of selected insulin products.

''(e) APPLICATION OF PATIENT PROTECTIONS.—The provisions of this title shall apply to selected insulin product benefits described in subsection (a) as though such benefits were required to be provided under section 2707(a).

''(f) OTHER REQUIREMENTS.—A group health plan or health insurance issuer offering group or individual health insurance coverage shall not impose, directly or through an entity providing services to the plan or coverage, any prior authorization or medical management requirement, or other similar conditions, on selected insulin products, except as clinically justified for safety reasons, to ensure reasonable quantity limits, and as specified by the Secretary.''.

(b) 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.—For plans years beginning on or after January 1, 2028, the exemption of coverage of selected insulin products (as defined in section 2729A of the Public Health Service Act) from the application of any deductible pursuant to section 2729(a)(1) of such Act, shall not be

treated as increasing the actuarial value of a plan when determining the actuarial value of a qualified health plan under this subsection.''.

(c) 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), for plan years beginning on or after January 1, 2028, a health plan described in paragraph (1) shall provide coverage of selected insulin products, in accordance with section 2729A 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 (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 2729A(b) of the Public Health Service Act; and

''(ii) the requirements of section 2729A 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).''.

(d) CONFORMING AMENDMENTS.—

(1) ERISA.—Section 715(a)(1) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185d(a)(1)) is amended by inserting ''and the INSULIN Act of 2026'' after ''Affordable Care Act''.

(2) IRC.—Section 9815(a)(1) of the Internal Revenue Code of 1986 is amended by inserting ''and the INSULIN Act of 2026'' after ''Affordable Care Act''.

SEC. 3. ADMINISTRATION.

(a) IMPLEMENTATION.—Notwithstanding any other provision of law, 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 title for plan years that begin on or after January 1, 2028, and end not later than January 1, 2030, by subregulatory guidance, program instruction, or otherwise.

(b) NON-APPLICATION OF THE PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code (commonly referred to as the ''Paperwork Reduction Act of 1995''), shall not apply to the provisions of, including the amendments made by, this title.

SEC. 4. GAO STUDY ON UNINSURED INDIVIDUALS WHO USE INSULIN.

The Comptroller General of the United States shall conduct a study, in consultation with patient, clinical, and provider groups and other experts, and not later than 2 years after the date of enactment of this Act, issue a report, on the characteristics of uninsured individuals who use insulin. Such study and report shall, to the extent data is available, include consideration of—

(1) any States or regions in which there is a higher prevalence of such individuals;

(2) any identifiable potential reasons for uninsured status;

(3) demographic characteristics of such individuals, such as race and ethnicity; and

(4) income level of such individuals.

SEC. 5. INSULIN RESOURCE CENTER AND HOTLINE FOR UNINSURED INDIVIDUALS.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Sec-

retary'') shall award a grant to an eligible entity for purposes of—

(1) establishing and maintaining a resource center of assistance programs offered by manufactures or other entities that are available to uninsured individuals seeking affordable insulin; and

(2) conducting the public education activities described in subsection (c)(7).

(b) ELIGIBLE ENTITIES.—To be eligible to receive the grant under subsection (a), an entity shall—

(1) be a trade, industry, or professional association, community- and consumer-focused nonprofit entity, or other entity, as determined by the Secretary that—

(A) is capable of carrying out the duties described in subsection (c);

(B) meets the standards described in subsection (e); and

(C) provides information consistent with the standards developed under subsection (f); and

(2) submit an application to the Secretary, at such time, in such manner, and containing such information as the Secretary may require, including information demonstrating that the entity—

(A) has existing relationships, or could readily establish relationships, with consumers (including uninsured individuals), health care providers, manufacturers of insulin, social service providers, pharmacies, and other experts that the Secretary determines appropriate, to meet the goals of this section; and

(B) has, or will establish, partnerships with, and solicit feedback from, other entities in other industries, professional associations, and community- and consumer-focused nonprofit organizations, to meet the goals of this section.

(c) DUTIES.—An entity that receives a grant under this section shall—

(1) distribute fair and impartial information concerning eligibility for manufacturer, foundational, and other assistance programs available to patients seeking affordable insulin;

(2) facilitate enrollment in manufacturer assistance programs or other assistance programs for uninsured individuals;

(3) make available to the public, through a standardized website, a clearinghouse of support available to patients, including—

(A) a link to Federally-qualified health centers and other providers, by ZIP Code;

(B) a link to retail community pharmacies, by ZIP Code; and

(C) information about how to enroll in health insurance;

(4) provide information in a manner that is culturally and linguistically appropriate;

(5) establish a hotline through which individuals may reach experts with questions about access to insulin, and that—

(A) is a 24/7 real-time hotline;

(B) provides voice and text support; and

(C) is staffed by navigators or licensed health care professionals;

(6) provide guidance to hospitals on how to share the website and hotline with patients; and

(7) conduct public education activities, in collaboration with the Department of Health and Human Services, to raise awareness of the availability of all manufacturer, foundational, and other assistance programs available to patients seeking affordable insulin, with a focus on uninsured individuals; including by—

(A) partnering with community health centers, hospitals, retail community pharmacies, and community-based organizations with a focus on access to affordable medicine; and

(B) working with State and local health departments to target the programs carried out using the grant to underserved communities.

(d) DUTIES OF THE SECRETARY.—The Secretary shall—

(1) ensure adequate maintenance of the resource center established by the entity receiving a grant under subsection (a);

(2) publicize such resource center on the website of the Department of Health and Human Services and across Federal agencies, as the Secretary determines appropriate; and

(3) ensure that such resource center meets the standards under subsection (e), and withdraw the grant and make an award to a different eligible entity in the case that an eligible entity fails to meet such standards.

(e) STANDARDS.—The Secretary shall establish standards for the resource center under this section, including provisions to ensure that the entity receiving a grant under this section is qualified to engage in the ac-

tivities described in this section and to avoid conflicts of interest. Under such standards, such entity—

(1) shall not—

(A) be a manufacturer of insulin products; or

(B) receive any consideration directly or indirectly from any manufacturer of insulin products in connection with the enrollment of any individuals in an assistance program; and

(2) shall provide information that is fair, accurate, and impartial.

(f) DATA COLLECTION AND EVALUATIONS.—The Secretary may collect data and conduct evaluations with respect to the services provided by the resource center described in this section for purposes of assessing the extent to which the provision of the services—

(1) reduces out of pocket insulin costs for uninsured individuals;

(2) increases awareness of assistance programs or foundational support available for uninsured individuals; and

(3) improves utilization of the resources described in paragraph (2) by uninsured individuals.

(g) REPORTS TO CONGRESS.—The Secretary shall submit to the Committee on Health, Education, Labor,

and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives, and make publicly available, annual reports on the activities carried out under this section, including any changes in the availability or scope of assistance programs offered by insulin manufacturers and information about the number of individuals who use the resource center, including the website or hotline.

(h) DEFINITIONS.—In this section—

(1) the term ''assistance program'' means a program to assist patients in obtaining a drug at a reduced cost, and includes third-party payments, financial assistance, discounts, product vouchers, and other reductions in out-of-pocket expenses;

(2) the term ''Federally-qualified health center'' has the meaning given such term in section 1905(l)(2) of the Social Security Act (42 U.S.C. 1396d(l)(2));

(3) 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 pursuant to such licensure;

(4) the term ''retail community pharmacy'' has the meaning given such term in section 1927(k)(10)

of the Social Security Act (42 U.S.C. 1396r–8(k)(10)); and

(5) the term ''uninsured individual'' means an individual who is not enrolled in coverage under a Federal health care program (as defined in section 1128B(f) of the Social Security Act (42 U.S.C. 1320a–7b(f))), the health program established under chapter 89 of title 5, United States Code, or a group health plan or group health insurance coverage (as defined in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91)).

(i) FUNDING.—To carry out this section, there are authorized to be appropriated $2,000,000 for each of fiscal years 2027 through 2032.

SEC. 6. EXPEDITING BIOSIMILAR COMPETITION.

(a) IN GENERAL.—Section 351(k) of the Public Health Service Act (42 U.S.C. 262(k)) is amended by adding at the end the following:

''(10) EXPEDITING BIOSIMILAR COMPETITION.—

''(A) IN GENERAL.—The Secretary may, at the request of the sponsor of an application under this subsection for licensure of a biosimilar biological product that is designated as a competitive biosimilar biological product pur-

suant to subparagraph (B), expedite the development and review of such application under this subsection.

"(B) DESIGNATION PROCESS.—

"(i) REQUEST.—The sponsor of an application under this subsection may request the Secretary to designate the drug as a competitive biosimilar biological product. A request for such designation may be made concurrently with, or during the 60-day period immediately prior to, the submission of a biosimilar biological product license application under this subsection.

"(ii) CRITERIA.—A biosimilar biological product is eligible for designation as a competitive biosimilar biological product under this paragraph if the Secretary determines that there is inadequate biosimilar competition.

"(iii) DESIGNATION.—Not later than 60 calendar days after the receipt of a request under clause (i), the Secretary may—

"(I) determine whether the biosimilar biological product that is the

subject of the request meets the criteria described in clause (ii); and

''(II) if the Secretary finds that such product meets such criteria, designate the biosimilar biological product as a competitive biosimilar biological product.

''(C) INADEQUATE BIOSIMILAR COMPETITION.—In this paragraph, the term 'inadequate biosimilar competition' means that, with respect to a biological product licensed under subsection (a)—

''(i) on the list published under paragraph (9)(A) (not including biological products on the discontinued section of such list), there are fewer than 3 biological products licensed under this subsection pursuant to an application that uses such biological product licensed under subsection (a) as a reference product; and

''(ii) not less than 3 years have passed since the expiration of all exclusivity periods applicable to such biological product licensed under subsection (a), or applicable to a biosimilar biological product licensed

under this subsection using such biological product licensed under subsection (a) as a reference product, including any exclusivity periods under—

"(I) paragraph (6);

"(II) paragraph (7)(A);

"(III) section 527 of the Federal Food, Drug, and Cosmetic Act; and

"(IV) subsection (m).".