Bill Cassidy, M.D.

AMENDMENT NO._____ Calendar No._____

Purpose: In the nature of a substitute.

IN THE SENATE OF THE UNITED STATES—119th Cong., 2d Sess.

S. 4189

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

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT IN THE NATURE OF A SUBSTITUTE intended to be proposed by _____

Viz:

Strike all after the enacting clause and insert the following:

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 insu-

lin 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. ENSURING TIMELY ACCESS TO GENERICS.

Section 505(q) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(q)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A)(i), by inserting ", 10.31," after "10.30";

(B) in subparagraph (E)—

(i) by striking "application and" and inserting "application or";

(ii) by striking "If the Secretary" and inserting the following:

"(i) IN GENERAL.—If the Secretary"; and

(iii) by striking the second sentence and inserting the following:

"(ii) PRIMARY PURPOSE OF DELAYING.—

"(I) IN GENERAL.—In determining whether a petition was submitted with the primary purpose of delaying an application, the Secretary may consider the following factors:

"(aa) Whether the petition was submitted in accordance with paragraph (2)(B), based on when the petitioner knew the relevant information relied upon to form the basis of such petition.

"(bb) When the petition was submitted in relation to when the petitioner reasonably should have known the relevant information

relied upon to form the basis of such petition.

"(cc) Whether the petitioner has submitted multiple or serial petitions or supplements to petitions raising issues that reasonably could have been known to the petitioner at the time of submission of the earlier petition or petitions.

"(dd) Whether the petition was submitted close in time to a known, first date upon which an application under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act could be approved.

"(ee) Whether the petition was submitted without relevant data or information in support of the scientific positions forming the basis of such petition.

"(ff) Whether the petition raises the same or substantially

similar issues as a prior petition to which the Secretary has responded substantively already, including if the subsequent submission follows such response from the Secretary closely in time.

"(gg) Whether the petition requests changing the applicable standards that other applicants are required to meet, including requesting testing, data, or labeling standards that are more onerous or rigorous than the standards the Secretary has determined to be applicable to the listed drug, reference product, or petitioner's version of the same drug.

"(hh) The petitioner's record of submitting petitions to the Food and Drug Administration that have been determined by the Secretary to have been submitted with the primary purpose of delay.

"(ii) Other relevant and appropriate factors, which the Secretary shall describe in guidance.

"(II) GUIDANCE.—The Secretary may issue or update guidance, as appropriate, to describe factors the Secretary considers in accordance with subclause (I).";

(C) by striking subparagraph (F);

(D) by redesignating subparagraphs (G) through (I) as subparagraphs (F) through (H), respectively; and

(E) in subparagraph (H), as so redesignated, by striking "submission of this petition" and inserting "submission of this document";

(2) in paragraph (2)—

(A) by redesignating subparagraphs (A) through (C) as subparagraphs (C) through (E), respectively;

(B) by inserting before subparagraph (C), as so redesignated, the following:

"(A) IN GENERAL.—A person shall submit a petition to the Secretary under paragraph (1) before filing a civil action in which the person seeks to set aside, delay, rescind, withdraw, or

prevent submission, review, or approval of an application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act. Such petition and any supplement to such a petition shall describe all information and arguments that form the basis of the relief requested in any civil action described in the previous sentence.

"(B) TIMELY SUBMISSION OF CITIZEN PETITION.—A petition and any supplement to a petition shall be submitted within 180 days after the person knew the information that forms the basis of the request made in the petition or supplement.";

(C) in subparagraph (C), as so redesignated—

(i) in the heading, by striking "WITHIN 150 DAYS";

(ii) in clause (i), by striking "during the 150-day period referred to in paragraph (1)(F),"; and

(iii) by amending clause (ii) to read as follows:

"(ii) on or after the date that is 151 days after the date of submission of the

petition, the Secretary approves or has approved the application that is the subject of the petition without having made such a final decision.";

(D) by amending subparagraph (D), as so redesignated, to read as follows:

"(D) DISMISSAL OF CERTAIN CIVIL ACTIONS.—

"(i) PETITION.—If a person files a civil action against the Secretary in which a person seeks to set aside, delay, rescind, withdraw, or prevent submission, review, or approval of an application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act without complying with the requirements of subparagraph (A), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies.

"(ii) TIMELINESS.—If a person files a civil action against the Secretary in which a person seeks to set aside, delay, rescind, withdraw, or prevent submission, review, or approval of an application submitted under subsection (b)(2) or (j) of this section or

section 351(k) of the Public Health Service Act without complying with the requirements of subparagraph (B), the court shall dismiss with prejudice the action for failure to timely file a petition.

"(iii) FINAL RESPONSE.—If a civil action is filed against the Secretary with respect to any issue raised in a petition timely filed under paragraph (1) in which the petitioner requests that the Secretary take any form of action that could, if taken, set aside, delay, rescind, withdraw, or prevent submission, review, or approval of an application submitted under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act before the Secretary has taken final agency action on the petition within the meaning of subparagraph (C), the court shall dismiss without prejudice the action for failure to exhaust administrative remedies."; and

(E) in clause (iii) of subparagraph (E), as so redesignated, by striking "as defined under subparagraph (2)(A)" and inserting "within the meaning of subparagraph (C)"; and

(3) in paragraph (4)—

(A) by striking "EXCEPTIONS" in the paragraph heading and all that follows through "This subsection does" and inserting "EXCEPTIONS.—This subsection does";

(B) by striking subparagraph (B); and

(C) by redesignating clauses (i) and (ii) as subparagraphs (A) and (B), respectively, and adjusting the margins accordingly.

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 pursuant 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, des-

ignate 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).".