S.L.C.
Sanders #6

AMENDMENT NO._____ Calendar No._____

Purpose: To promote the affordability of insulin.

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

S. 3014

To amend the Federal Food, Drug, and Cosmetic Act with respect to citizen petitions.

Referred to the Committee on _____ and ordered to be printed

Ordered to lie on the table and to be printed

AMENDMENT intended to be proposed by _____

Viz:

At the appropriate place, insert the following:

TITLE II—INSULIN AFFORDABILITY

Subtitle A—Commercial Market Patient Protections

SEC. 201. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

(a) 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–12. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

"(a) IN GENERAL.—For plan years beginning on or after January 1, 2027, 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, 2027, at least one of each dosage form (such as vial, pen, or inhaler dosage forms) 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 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.

"(d) RULE OF CONSTRUCTION.—Subsection (a) shall not be construed to 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 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 or coverage.

"(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 pharmacy benefit management services, any prior authorization or other 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 2799A–12(b) of the Public Health Service Act) from the application of any deductible pursuant to section 2799A–12(a)(1) of such Act, section 727(a)(1) of the Employee Retirement Income Security Act of 1974, or section 9827(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 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, 2027, a health plan described in paragraph (1) shall provide coverage of selected insulin products, in accordance with section 2799A–12 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 2799A–12(b) of the Public Health Service Act; and

"(ii) the requirements of section 2799A–12 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) ERISA.—

(1) 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. 727. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

"(a) IN GENERAL.—For plan years beginning on or after January 1, 2027, 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 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, 2027, at least one of each dosage form (such as vial, pen, or inhaler dosage forms) 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 of the Public Health Service Act (42 U.S.C. 262) 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.

"(d) RULE OF CONSTRUCTION.—Subsection (a) shall not be construed to 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 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 or coverage.

"(f) OTHER REQUIREMENTS.—A group health plan or health insurance issuer offering group health insurance coverage shall not impose, directly or through an entity providing pharmacy benefit management services, any prior authorization or other 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.".

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.) is amended by inserting after the item relating to section 726 the following:

"Sec. 727. Requirements with respect to cost-sharing for certain insulin products.".

(e) INTERNAL REVENUE CODE.—

(1) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following:

"SEC. 9827. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

"(a) IN GENERAL.—For plan years beginning on or after January 1, 2027, 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 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, including price concessions received by or on behalf of third-party entities providing services to the plan, 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, 2027, at least one of each dosage form (such as vial, pen, or inhaler dosage forms) 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.

"(2) INSULIN.—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.

"(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.

"(f) OTHER REQUIREMENTS.—A group health plan shall not impose, directly or through an entity providing pharmacy benefit management services, any prior authorization or other 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.".

(2) 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. 9827. Requirements with respect to cost-sharing for certain insulin products.".

SEC. 202. APPLICATION TO RETIREE AND CERTAIN SMALL GROUP PLANS.

(a) ERISA.—Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191a(a)) is amended by striking "and 726" and inserting "726, and 727".

(b) IRC.—The Internal Revenue Code of 1986 is amended—

(1) in section 9831(a)(2), by striking "section 9826" and inserting "sections 9811, 9826, and 9827"; and

(2) in section 4980D(d)(1), by striking "section 9811" and inserting "section 9811 or 9827".

SEC. 203. 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 subtitle for plan years that begin on or after January 1, 2027, 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 subtitle.

Subtitle B—Pharmacy Benefit Manager Transparency and Rebate Reform

SEC. 211. FULL REBATE ON INSULIN PASS-THROUGH TO PLAN.

(a) PHSA.—Part D of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–111 et seq.), as amended by section 201, is further amended by adding at the end the following:

"SEC. 2799A–13. FULL REBATE ON INSULIN PASS-THROUGH TO PLAN.

"(a) IN GENERAL.—A pharmacy benefits manager, a third-party administrator of a group health plan, a health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefits management services under such health plan or health insurance coverage shall remit 100 percent of rebates, fees, alternative discounts, and all other remuneration received from a pharmaceutical manufacturer, distributor or any other third party, that are related to utilization of insulin

under such health plan or health insurance coverage, to the group health plan.

"(b) FORM AND MANNER OF REMITTANCE.—Such rebates, fees, alternative discounts, and other remuneration shall be—

"(1) remitted to the group health plan in a timely fashion after the period for which such rebates, fees, or other remuneration is calculated, and in no case later than 90 days after the end of such period;

"(2) fully disclosed and enumerated to the group health plan sponsor; and

"(3) available for audit by the plan sponsor, or a third-party designated by a plan sponsor no less than once per plan year.".

(b) ERISA.—

(1) 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.), as amended by section 201, is further amended by adding at the end the following:

"SEC. 728. FULL REBATE ON INSULIN PASS-THROUGH TO PLAN.

"(a) IN GENERAL.—A pharmacy benefits manager, a third-party administrator of a group health plan, a

health insurance issuer offering group health insurance coverage, or an entity providing pharmacy benefits management services under such health plan or health insurance coverage shall remit 100 percent of rebates, fees, alternative discounts, and all other remuneration received from a pharmaceutical manufacturer, distributor or any other third party, that are related to utilization of insulin under such health plan or health insurance coverage, to the group health plan.

"(b) FORM AND MANNER OF REMITTANCE.—Such rebates, fees, alternative discounts, and other remuneration shall be—

"(1) remitted to the group health plan in a timely fashion after the period for which such rebates, fees, or other remuneration is calculated, and in no case later than 90 days after the end of such period;

"(2) fully disclosed and enumerated to the group health plan sponsor; and

"(3) available for audit by the plan sponsor, or a third-party designated by a plan sponsor no less than once per plan year.".

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.),

as amended by section 201, is further amended by inserting after the item relating to section 727 the following:

"Sec. 728. Full rebate on insulin pass-through to plan.".

(c) INTERNAL REVENUE CODE.—

(1) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by section 201, is further amended by adding at the end the following new section:

"SEC. 9828. FULL REBATE ON INSULIN PASS-THROUGH TO PLAN.

"(a) IN GENERAL.—A pharmacy benefits manager, a third-party administrator of a group health plan, or an entity providing pharmacy benefits management services under such health plan shall remit 100 percent of rebates, fees, alternative discounts, and all other remuneration received from a pharmaceutical manufacturer, distributor or any other third party, that are related to utilization of insulin under such health plan, to the group health plan.

"(b) FORM AND MANNER OF REMITTANCE.—Such rebates, fees, alternative discounts, and other remuneration shall be—

"(1) remitted to the group health plan in a timely fashion after the period for which such rebates, fees, or other remuneration is calculated, and

in no case later than 90 days after the end of such period;

"(2) fully disclosed and enumerated to the group health plan sponsor; and

"(3) available for audit by the plan sponsor, or a third-party designated by a plan sponsor no less than once per plan year.".

(2) CLERICAL AMENDMENT.—The table of sections for subchapter B of chapter 100 of such Code, as amended by section 201, is further amended by adding at the end the following new item:

"Sec. 9828. Full rebate on insulin pass-through to plan.".

Subtitle C—Programs for Providing Affordable Insulin to Uninsured Individuals

SEC. 221. PILOT PROGRAM FOR PROVIDING AFFORDABLE INSULIN TO UNINSURED INDIVIDUALS.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

"SEC. 399V–8. PILOT PROGRAM FOR PROVIDING AFFORDABLE INSULIN TO UNINSURED INDIVIDUALS.

"(a) IN GENERAL.—The Secretary shall conduct a 5-year pilot program under which the Secretary awards grants to 10 States for purposes of providing affordable insulin to uninsured individuals.

"(b) AWARDS.—The Secretary shall award grants under this section to 10 States that—

"(1) submit an application to the Secretary, at such time, in such manner, and containing such information as the Secretary may require; and

"(2) have high rates of uninsured individuals and individuals diagnosed with diabetes, which may include high rates of newly diagnosed diabetes.

"(c) USE OF FUNDS.—A State shall use the grant funds received under this section for any of the following purposes:

"(1) To assist in the purchase or dispensing of insulin, through Federally qualified health centers and retail community pharmacies, for uninsured individuals.

"(2) To enroll individuals in programs under which drug manufacturers provide financial or medication assistance to low-income individuals, in order to assist such individuals in obtaining insulin.

"(3) To allow Federally qualified health centers to establish new, or maintain or expand existing, on-site pharmacies owned and operated by the health center that provide low-cost insulin to patients, and to allow retail community pharmacies to provide low-cost insulin to patients.

"(4) To engage in other activities to assist uninsured individuals in obtaining insulin, as the Secretary determines appropriate.

"(d) FORMULA.—The Secretary shall establish a formula for purposes of determining the grant amount under this section for each State. Such formula shall—

"(1) provide for a minimum amount that will be provided to each State; and

"(2) take into account the rates of individuals with type 1 or type 2, insulin-dependent diabetes and of uninsured individuals in each State for purposes of determining any additional amounts provided to a State.

"(e) ACCOUNTABILITY AND OVERSIGHT.—A State receiving a grant under this section shall, not later than 1 year after receiving the grant, submit a report to the Secretary that includes—

"(1) a description of the purposes for which the grant funds received by the State were expended in the preceding fiscal year, and the activities of the State under the grant during such year; and

"(2) the number of individuals served through the grant.

"(f) DEFINITIONS.—In this section:

"(1) AFFORDABLE.—The term 'affordable', with respect to insulin, means that the out-of-pocket cost to the individual for the insulin is not more than $35 per 1-month supply.

"(2) FEDERALLY-QUALIFIED HEALTH CENTER.—The term 'Federally-qualified health center' has the meaning given such term in section 1905(l)(2) of the Social Security Act.

"(3) INSULIN.—The term 'insulin' means insulin that is licensed under subsection (a) or (k) of section 351 and continues to be marketed under such section.

"(4) RETAIL COMMUNITY PHARMACY.—The term 'retail community pharmacy' has the meaning given such term in section 1927(k)(10) of the Social Security Act.

"(5) UNINSURED INDIVIDUAL.—The term 'uninsured individual' means an individual who—

"(A) is a citizen of the United States or a qualified alien (as defined in section 431(b) of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996);

"(B) does not qualify for coverage under a Federal health care program (as defined in section 1128B(f) of the Social Security Act), 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); and

"(C) is not entitled to a premium assistance tax credit under section 36B of the Internal Revenue Code of 1986.

"(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $100,000,000 for fiscal year 2027, to remain available until expended.".

SEC. 222. GAO STUDY ON UNINSURED INDIVIDUALS WHO USE INSULIN.

(a) IN GENERAL.—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.

(b) DEFINITIONS.—In this section, the terms "insulin" and "uninsured individual" have the meanings given such terms in section 399V–8 of the Public Health Service Act, as added by section 221.

SEC. 223. 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 "Secretary") 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 (e);

(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 activities 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—

(A) does not qualify for 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)); and

(B) is not entitled to a premium assistance tax credit under section 36B of the Internal Revenue Code of 1986.

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