

Bar Sanders

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:

1 At the appropriate place, insert the following:

2 **TITLE II—INSULIN**

3 **AFFORDABILITY**

4 **Subtitle A—Commercial Market**

5 **Patient Protections**

6 **SEC. 201. REQUIREMENTS WITH RESPECT TO COST-SHAR-**

7 **ING FOR CERTAIN INSULIN PRODUCTS.**

8 (a) IN GENERAL.—Part D of title XXVII of the Pub-
9 lic Health Service Act (42 U.S.C. 300gg–111 et seq.) is
10 amended by adding at the end the following:

1 **“SEC. 2799A-12. REQUIREMENTS WITH RESPECT TO COST-**
2 **SHARING FOR CERTAIN INSULIN PRODUCTS.**

3 “(a) IN GENERAL.—For plan years beginning on or
4 after January 1, 2027, a group health plan or health in-
5 surance issuer offering group or individual health insur-
6 ance coverage shall provide coverage of selected insulin
7 products, and with respect to such products, shall not—

8 “(1) apply any deductible; or

9 “(2) impose any cost-sharing requirements in
10 excess of, per 30-day supply—

11 “(A) for any applicable plan year begin-
12 ning before January 1, 2028, \$35; or

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

15 “(i) \$35; or

16 “(ii) the amount equal to 25 percent
17 of the negotiated price of the selected insu-
18 lin product net of all price concessions re-
19 ceived by or on behalf of the plan or issuer,
20 including price concessions received by or
21 on behalf of third-party entities providing
22 services to the plan or issuer, such as
23 pharmacy benefit management services or
24 third party administrators.

25 “(b) DEFINITIONS.—In this section:

1 “(1) SELECTED INSULIN PRODUCTS.—The term
2 ‘selected insulin products’ means, for any plan year
3 beginning on or after January 1, 2027, at least one
4 of each dosage form (such as vial, pen, or inhaler
5 dosage forms) of each different type (such as rapid-
6 acting, short-acting, intermediate-acting, long-acting,
7 and pre-mixed) of insulin, when such form is li-
8 censed and marketed, as selected by the group
9 health plan or health insurance issuer.

10 “(2) INSULIN.—The term ‘insulin’ means insu-
11 lin that is licensed under subsection (a) or (k) of
12 section 351 and continues to be marketed pursuant
13 to such licensure.

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

23 “(d) RULE OF CONSTRUCTION.—Subsection (a) shall
24 not be construed to require coverage of, or prevent a group
25 health plan or health insurance issuer from imposing cost-

1 sharing other than the levels specified in subsection (a)
2 on, insulin products that are not selected insulin products,
3 to the extent that such coverage is not otherwise required
4 and such cost-sharing is otherwise permitted under Fed-
5 eral and applicable State law.

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

11 “(f) OTHER REQUIREMENTS.—A group health plan
12 or health insurance issuer offering group or individual
13 health insurance coverage shall not impose, directly or
14 through an entity providing pharmacy benefit manage-
15 ment services, any prior authorization or other medical
16 management requirement, or other similar conditions, on
17 selected insulin products, except as clinically justified for
18 safety reasons, to ensure reasonable quantity limits and
19 as specified by the Secretary.”.

20 (b) NO EFFECT ON OTHER COST-SHARING.—Section
21 1302(d)(2) of the Patient Protection and Affordable Care
22 Act (42 U.S.C. 18022(d)(2)) is amended by adding at the
23 end the following new subparagraph:

24 “(D) SPECIAL RULE RELATING TO INSU-
25 LIN COVERAGE.—For plans years beginning on

1 or after January 1, 2028, the exemption of cov-
2 erage of selected insulin products (as defined in
3 section 2799A–12(b) of the Public Health Serv-
4 ice Act) from the application of any deductible
5 pursuant to section 2799A–12(a)(1) of such
6 Act, section 727(a)(1) of the Employee Retire-
7 ment Income Security Act of 1974, or section
8 9827(a)(1) of the Internal Revenue Code of
9 1986 shall not be considered when determining
10 the actuarial value of a qualified health plan
11 under this subsection.”.

12 (c) COVERAGE OF CERTAIN INSULIN PRODUCTS
13 UNDER CATASTROPHIC PLANS.—Section 1302(e) of the
14 Patient Protection and Affordable Care Act (42 U.S.C.
15 18022(e)) is amended by adding at the end the following:

16 “(4) COVERAGE OF CERTAIN INSULIN PROD-
17 UCTS.—

18 “(A) IN GENERAL.—Notwithstanding para-
19 graph (1)(B)(i), for plan years beginning on or
20 after January 1, 2027, a health plan described
21 in paragraph (1) shall provide coverage of se-
22 lected insulin products, in accordance with sec-
23 tion 2799A–12 of the Public Health Service
24 Act, before an enrolled individual has incurred,
25 during the plan year, cost-sharing expenses in

1 an amount equal to the annual limitation in ef-
2 fect under subsection (c)(1) for the plan year.

3 “(B) TERMINOLOGY.—For purposes of
4 subparagraph (A)—

5 “(i) the term ‘selected insulin prod-
6 ucts’ has the meaning given such term in
7 section 2799A–12(b) of the Public Health
8 Service Act; and

9 “(ii) the requirements of section
10 2799A–12 of such Act shall be applied by
11 deeming each reference in such section to
12 ‘individual health insurance coverage’ to be
13 a reference to a plan described in para-
14 graph (1).”.

15 (d) ERISA.—

16 (1) IN GENERAL.—Subpart B of part 7 of sub-
17 title B of title I of the Employee Retirement Income
18 Security Act of 1974 (29 U.S.C. 1185 et seq.) is
19 amended by adding at the end the following:

20 **“SEC. 727. REQUIREMENTS WITH RESPECT TO COST-SHAR-**
21 **ING FOR CERTAIN INSULIN PRODUCTS.**

22 “(a) IN GENERAL.—For plan years beginning on or
23 after January 1, 2027, a group health plan or health in-
24 surance issuer offering group health insurance coverage

1 shall provide coverage of selected insulin products, and
2 with respect to such products, shall not—

3 “(1) apply any deductible; or

4 “(2) impose any cost-sharing requirements in
5 excess of, per 30-day supply—

6 “(A) for any applicable plan year begin-
7 ning before January 1, 2028, \$35; or

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

10 “(i) \$35; or

11 “(ii) the amount equal to 25 percent
12 of the negotiated price of the selected insu-
13 lin product net of all price concessions re-
14 ceived by or on behalf of the plan or issuer,
15 including price concessions received by or
16 on behalf of third-party entities providing
17 services to the plan or issuer, such as
18 pharmacy benefit management services or
19 third party administrators.

20 “(b) DEFINITIONS.—In this section:

21 “(1) SELECTED INSULIN PRODUCTS.—The term
22 ‘selected insulin products’ means, for any plan year
23 beginning on or after January 1, 2027, at least one
24 of each dosage form (such as vial, pen, or inhaler
25 dosage forms) of each different type (such as rapid-

1 acting, short-acting, intermediate-acting, long-acting,
2 and pre-mixed) of insulin, when such form is li-
3 censed and marketed, as selected by the group
4 health plan or health insurance issuer.

5 “(2) INSULIN.—The term ‘insulin’ means insu-
6 lin that is licensed under subsection (a) or (k) of
7 section 351 of the Public Health Service Act (42
8 U.S.C. 262) and continues to be marketed pursuant
9 to such licensure.

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

19 “(d) RULE OF CONSTRUCTION.—Subsection (a) shall
20 not be construed to require coverage of, or prevent a group
21 health plan or health insurance issuer from imposing cost-
22 sharing other than the levels specified in subsection (a)
23 on, insulin products that are not selected insulin products,
24 to the extent that such coverage is not otherwise required

1 and such cost-sharing is otherwise permitted under Fed-
2 eral and applicable State law.

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

8 “(f) OTHER REQUIREMENTS.—A group health plan
9 or health insurance issuer offering group health insurance
10 coverage shall not impose, directly or through an entity
11 providing pharmacy benefit management services, any
12 prior authorization or other medical management require-
13 ment, or other similar conditions, on selected insulin prod-
14 ucts, except as clinically justified for safety reasons, to en-
15 sure reasonable quantity limits and as specified by the
16 Secretary.”.

17 (2) CLERICAL AMENDMENT.—The table of con-
18 tents in section 1 of the Employee Retirement In-
19 come Security Act of 1974 (29 U.S.C. 1001 et seq.)
20 is amended by inserting after the item relating to
21 section 726 the following:

“Sec. 727. Requirements with respect to cost-sharing for certain insulin prod-
ucts.”.

22 (e) INTERNAL REVENUE CODE.—

1 (1) IN GENERAL.—Subchapter B of chapter
2 100 of the Internal Revenue Code of 1986 is amend-
3 ed by adding at the end the following:

4 **“SEC. 9827. REQUIREMENTS WITH RESPECT TO COST-SHAR-**
5 **ING FOR CERTAIN INSULIN PRODUCTS.**

6 “(a) IN GENERAL.—For plan years beginning on or
7 after January 1, 2027, a group health plan shall provide
8 coverage of selected insulin products, and with respect to
9 such products, shall not—

10 “(1) apply any deductible; or

11 “(2) impose any cost-sharing requirements in
12 excess of, per 30-day supply—

13 “(A) for any applicable plan year begin-
14 ning before January 1, 2028, \$35; or

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

17 “(i) \$35; or

18 “(ii) the amount equal to 25 percent
19 of the negotiated price of the selected insu-
20 lin product net of all price concessions re-
21 ceived by or on behalf of the plan, includ-
22 ing price concessions received by or on be-
23 half of third-party entities providing serv-
24 ices to the plan, such as pharmacy benefit

1 management services or third party admin-
2 istrators.

3 “(b) DEFINITIONS.—In this section:

4 “(1) SELECTED INSULIN PRODUCTS.—The term
5 ‘selected insulin products’ means, for any plan year
6 beginning on or after January 1, 2027, at least one
7 of each dosage form (such as vial, pen, or inhaler
8 dosage forms) of each different type (such as rapid-
9 acting, short-acting, intermediate-acting, long-acting,
10 and pre-mixed) of insulin, when such form is li-
11 censed and marketed, as selected by the group
12 health plan.

13 “(2) INSULIN.—The term ‘insulin’ means insu-
14 lin that is licensed under subsection (a) or (k) of
15 section 351 of the Public Health Service Act (42
16 U.S.C. 262) and continues to be marketed pursuant
17 to such licensure.

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

1 in this section that are delivered by an out-of-network pro-
2 vider.

3 “(d) RULE OF CONSTRUCTION.—Subsection (a) shall
4 not be construed to require coverage of, or prevent a group
5 health plan from imposing cost-sharing other than the lev-
6 els specified in subsection (a) on, insulin products that are
7 not selected insulin products, to the extent that such cov-
8 erage is not otherwise required and such cost-sharing is
9 otherwise permitted under Federal and applicable State
10 law.

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

16 “(f) OTHER REQUIREMENTS.—A group health plan
17 shall not impose, directly or through an entity providing
18 pharmacy benefit management services, any prior author-
19 ization or other medical management requirement, or
20 other similar conditions, on selected insulin products, ex-
21 cept as clinically justified for safety reasons, to ensure rea-
22 sonable quantity limits and as specified by the Secretary.”.

23 (2) CLERICAL AMENDMENT.—The table of sec-
24 tions for subchapter B of chapter 100 of such Code

1 is amended by adding at the end the following new
2 item:

“Sec. 9827. Requirements with respect to cost-sharing for certain insulin products.”.

3 **SEC. 202. APPLICATION TO RETIREE AND CERTAIN SMALL**
4 **GROUP PLANS.**

5 (a) ERISA.—Section 732(a) of the Employee Retirement
6 Income Security Act of 1974 (29 U.S.C. 1191a(a))
7 is amended by striking “and 726” and inserting “726, and
8 727”.

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

11 (1) in section 9831(a)(2), by striking “section
12 9826” and inserting “sections 9811, 9826, and
13 9827”; and

14 (2) in section 4980D(d)(1), by striking “section
15 9811” and inserting “section 9811 or 9827”.

16 **SEC. 203. ADMINISTRATION.**

17 (a) IMPLEMENTATION.—Notwithstanding any other
18 provision of law, the Secretary of Health and Human
19 Services, the Secretary of Labor, and the Secretary of the
20 Treasury may implement the provisions of, including the
21 amendments made by, this subtitle for plan years that
22 begin on or after January 1, 2027, and end not later than
23 January 1, 2030, by subregulatory guidance, program in-
24 struction, or otherwise.

1 (b) NON-APPLICATION OF THE PAPERWORK REDUC-
2 TION ACT.—Chapter 35 of title 44, United States Code
3 (commonly referred to as the “Paperwork Reduction Act
4 of 1995”), shall not apply to the provisions of, including
5 the amendments made by, this subtitle.

6 **Subtitle B—Pharmacy Benefit Man-**
7 **ager Transparency and Rebate**
8 **Reform**

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

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

15 **“SEC. 2799A-13. FULL REBATE ON INSULIN PASS-THROUGH**
16 **TO PLAN.**

17 “(a) IN GENERAL.—A pharmacy benefits manager,
18 a third-party administrator of a group health plan, a
19 health insurance issuer offering group health insurance
20 coverage, or an entity providing pharmacy benefits man-
21 agement services under such health plan or health insur-
22 ance coverage shall remit 100 percent of rebates, fees, al-
23 ternative discounts, and all other remuneration received
24 from a pharmaceutical manufacturer, distributor or any
25 other third party, that are related to utilization of insulin

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

3 “(b) FORM AND MANNER OF REMITTANCE.—Such
4 rebates, fees, alternative discounts, and other remunera-
5 tion shall be—

6 “(1) remitted to the group health plan in a
7 timely fashion after the period for which such re-
8 bates, fees, or other remuneration is calculated, and
9 in no case later than 90 days after the end of such
10 period;

11 “(2) fully disclosed and enumerated to the
12 group health plan sponsor; and

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

16 (b) ERISA.—

17 (1) IN GENERAL.—Subpart B of part 7 of sub-
18 title B of title I of the Employee Retirement Income
19 Security Act of 1974 (29 U.S.C. 1185 et seq.), as
20 amended by section 201, is further amended by add-
21 ing at the end the following:

22 **“SEC. 728. FULL REBATE ON INSULIN PASS-THROUGH TO**
23 **PLAN.**

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

1 health insurance issuer offering group health insurance
2 coverage, or an entity providing pharmacy benefits man-
3 agement services under such health plan or health insur-
4 ance coverage shall remit 100 percent of rebates, fees, al-
5 ternative discounts, and all other remuneration received
6 from a pharmaceutical manufacturer, distributor or any
7 other third party, that are related to utilization of insulin
8 under such health plan or health insurance coverage, to
9 the group health plan.

10 “(b) FORM AND MANNER OF REMITTANCE.—Such
11 rebates, fees, alternative discounts, and other remunera-
12 tion shall be—

13 “(1) remitted to the group health plan in a
14 timely fashion after the period for which such re-
15 bates, fees, or other remuneration is calculated, and
16 in no case later than 90 days after the end of such
17 period;

18 “(2) fully disclosed and enumerated to the
19 group health plan sponsor; and

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

23 (2) CLERICAL AMENDMENT.—The table of con-
24 tents in section 1 of the Employee Retirement In-
25 come Security Act of 1974 (29 U.S.C. 1001 et seq.),

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

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

4 (c) INTERNAL REVENUE CODE.—

5 (1) IN GENERAL.—Subchapter B of chapter
6 100 of the Internal Revenue Code of 1986, as
7 amended by section 201, is further amended by add-
8 ing at the end the following new section:

9 **“SEC. 9828. FULL REBATE ON INSULIN PASS-THROUGH TO**
10 **PLAN.**

11 “(a) IN GENERAL.—A pharmacy benefits manager,
12 a third-party administrator of a group health plan, or an
13 entity providing pharmacy benefits management services
14 under such health plan shall remit 100 percent of rebates,
15 fees, alternative discounts, and all other remuneration re-
16 ceived from a pharmaceutical manufacturer, distributor or
17 any other third party, that are related to utilization of in-
18 sulin under such health plan, to the group health plan.

19 “(b) FORM AND MANNER OF REMITTANCE.—Such
20 rebates, fees, alternative discounts, and other remunera-
21 tion shall be—

22 “(1) remitted to the group health plan in a
23 timely fashion after the period for which such re-
24 bates, fees, or other remuneration is calculated, and

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

3 “(2) fully disclosed and enumerated to the
4 group health plan sponsor; and

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

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

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

12 **Subtitle C—Programs for Pro-**
13 **viding Affordable Insulin to Un-**
14 **insured Individuals**

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

17 Part P of title III of the Public Health Service Act
18 (42 U.S.C. 280g et seq.) is amended by adding at the end
19 the following:

20 **“SEC. 399V-8. PILOT PROGRAM FOR PROVIDING AFFORD-**
21 **ABLE INSULIN TO UNINSURED INDIVIDUALS.**

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

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

3 “(1) submit an application to the Secretary, at
4 such time, in such manner, and containing such in-
5 formation as the Secretary may require; and

6 “(2) have high rates of uninsured individuals
7 and individuals diagnosed with diabetes, which may
8 include high rates of newly diagnosed diabetes.

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

12 “(1) To assist in the purchase or dispensing of
13 insulin, through Federally qualified health centers
14 and retail community pharmacies, for uninsured in-
15 dividuals.

16 “(2) To enroll individuals in programs under
17 which drug manufacturers provide financial or medi-
18 cation assistance to low-income individuals, in order
19 to assist such individuals in obtaining insulin.

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

1 “(4) To engage in other activities to assist un-
2 insured individuals in obtaining insulin, as the Sec-
3 retary determines appropriate.

4 “(d) FORMULA.—The Secretary shall establish a for-
5 mula for purposes of determining the grant amount under
6 this section for each State. Such formula shall—

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

9 “(2) take into account the rates of individuals
10 with type 1 or type 2, insulin-dependent diabetes
11 and of uninsured individuals in each State for pur-
12 poses of determining any additional amounts pro-
13 vided to a State.

14 “(e) ACCOUNTABILITY AND OVERSIGHT.—A State
15 receiving a grant under this section shall, not later than
16 1 year after receiving the grant, submit a report to the
17 Secretary that includes—

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

22 “(2) the number of individuals served through
23 the grant.

24 “(f) DEFINITIONS.—In this section:

1 “(1) AFFORDABLE.—The term ‘affordable’,
2 with respect to insulin, means that the out-of-pocket
3 cost to the individual for the insulin is not more
4 than \$35 per 1-month supply.

5 “(2) FEDERALLY-QUALIFIED HEALTH CEN-
6 TER.—The term ‘Federally-qualified health center’
7 has the meaning given such term in section
8 1905(l)(2) of the Social Security Act.

9 “(3) INSULIN.—The term ‘insulin’ means insu-
10 lin that is licensed under subsection (a) or (k) of
11 section 351 and continues to be marketed under
12 such section.

13 “(4) RETAIL COMMUNITY PHARMACY.—The
14 term ‘retail community pharmacy’ has the meaning
15 given such term in section 1927(k)(10) of the Social
16 Security Act.

17 “(5) UNINSURED INDIVIDUAL.—The term ‘un-
18 insured individual’ means an individual who—

19 “(A) is a citizen of the United States or a
20 qualified alien (as defined in section 431(b) of
21 the Personal Responsibility and Work Oppor-
22 tunity Reconciliation Act of 1996);

23 “(B) does not qualify for coverage under a
24 Federal health care program (as defined in sec-
25 tion 1128B(f) of the Social Security Act), the

1 health program established under chapter 89 of
2 title 5, United States Code, or a group health
3 plan or group health insurance coverage (as de-
4 fined in section 2791); and

5 “(C) is not entitled to a premium assist-
6 ance tax credit under section 36B of the Inter-
7 nal Revenue Code of 1986.

8 “(g) AUTHORIZATION OF APPROPRIATIONS.—To
9 carry out this section, there is authorized to be appro-
10 priated \$100,000,000 for fiscal year 2027, to remain
11 available until expended.”.

12 **SEC. 222. GAO STUDY ON UNINSURED INDIVIDUALS WHO**
13 **USE INSULIN.**

14 (a) IN GENERAL.—The Comptroller General of the
15 United States shall conduct a study, in consultation with
16 patient, clinical, and provider groups and other experts,
17 and not later than 2 years after the date of enactment
18 of this Act, issue a report, on the characteristics of unin-
19 sured individuals who use insulin. Such study and report
20 shall, to the extent data is available, include consideration
21 of—

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

24 (2) any identifiable potential reasons for unin-
25 sured status;

- 1 (3) demographic characteristics of such individ-
2 uals, such as race and ethnicity; and
3 (4) income level of such individuals.

4 (b) DEFINITIONS.—In this section, the terms “insu-
5 lin” and “uninsured individual” have the meanings given
6 such terms in section 399V–8 of the Public Health Service
7 Act, as added by section 221.

8 **SEC. 223. INSULIN RESOURCE CENTER AND HOTLINE FOR**
9 **UNINSURED INDIVIDUALS.**

10 (a) IN GENERAL.—The Secretary of Health and
11 Human Services (referred to in this section as the “Sec-
12 retary”) shall award a grant to an eligible entity for pur-
13 poses of—

- 14 (1) establishing and maintaining a resource
15 center of assistance programs offered by manufac-
16 tures or other entities that are available to unin-
17 sured individuals seeking affordable insulin; and
18 (2) conducting the public education activities
19 described in subsection (c)(7).

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

- 22 (1) be a trade, industry, or professional associa-
23 tion, community- and consumer-focused nonprofit
24 entity, or other entity, as determined by the Sec-
25 retary that—

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

3 (B) meets the standards described in sub-
4 section (e); and

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

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

12 (A) has existing relationships, or could
13 readily establish relationships, with consumers
14 (including uninsured individuals), health care
15 providers, manufacturers of insulin, social serv-
16 ice providers, pharmacies, and other experts
17 that the Secretary determines appropriate, to
18 meet the goals of this section; and

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

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

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

5 (2) facilitate enrollment in manufacturer assist-
6 ance programs or other assistance programs for un-
7 insured individuals;

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

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

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

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

17 (4) provide information in a manner that is cul-
18 turally and linguistically appropriate;

19 (5) establish a hotline through which individ-
20 uals may reach experts with questions about access
21 to insulin, and that—

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

23 (B) provides voice and text support; and

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

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

3 (7) conduct public education activities, in col-
4 laboration with the Department of Health and
5 Human Services, to raise awareness of the avail-
6 ability of all manufacturer, foundational, and other
7 assistance programs available to patients seeking af-
8 fordable insulin, with a focus on uninsured individ-
9 uals; including by—

10 (A) partnering with community health cen-
11 ters, hospitals, retail community pharmacies,
12 and community-based organizations with a
13 focus on access to affordable medicine; and

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

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

19 (1) ensure adequate maintenance of the re-
20 source center established by the entity receiving a
21 grant under subsection (a);

22 (2) publicize such resource center on the
23 website of the Department of Health and Human
24 Services and across Federal agencies, as the Sec-
25 retary determines appropriate; and

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

6 (e) STANDARDS.—The Secretary shall establish
7 standards for the resource center under this section, in-
8 cluding provisions to ensure that the entity receiving a
9 grant under this section is qualified to engage in the ac-
10 tivities described in this section and to avoid conflicts of
11 interest. Under such standards, such entity—

12 (1) shall not—

13 (A) be a manufacturer of insulin products;
14 or

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

19 (2) shall provide information that is fair, accu-
20 rate, and impartial.

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

1 (1) reduces out of pocket insulin costs for unin-
2 sured individuals;

3 (2) increases awareness of assistance programs
4 or foundational support available for uninsured indi-
5 viduals; and

6 (3) improves utilization of the resources de-
7 scribed in paragraph (2) by uninsured individuals.

8 (g) REPORTS TO CONGRESS.—The Secretary shall
9 submit to the Committee on Health, Education, Labor,
10 and Pensions and the Committee on Appropriations of the
11 Senate and the Committee on Energy and Commerce and
12 the Committee on Appropriations of the House of Rep-
13 resentatives, and make publicly available, annual reports
14 on the activities carried out under this section, including
15 any changes in the availability or scope of assistance pro-
16 grams offered by insulin manufacturers and information
17 about the number of individuals who use the resource cen-
18 ter, including the website or hotline.

19 (h) DEFINITIONS.—In this section—

20 (1) the term “assistance program” means a
21 program to assist patients in obtaining a drug at a
22 reduced cost, and includes third-party payments, fi-
23 nancial assistance, discounts, product vouchers, and
24 other reductions in out-of-pocket expenses;

1 (2) the term “Federally-qualified health center”
2 has the meaning given such term in section
3 1905(l)(2) of the Social Security Act (42 U.S.C.
4 1396d(l)(2));

5 (3) the term “insulin” means insulin that is li-
6 censed under subsection (a) or (k) of section 351 of
7 the Public Health Service Act (42 U.S.C. 262) and
8 continues to be marketed pursuant to such licensure;

9 (4) the term “retail community pharmacy” has
10 the meaning given such term in section 1927(k)(10)
11 of the Social Security Act (42 U.S.C. 1396r-
12 8(k)(10)); and

13 (5) the term “uninsured individual” means an
14 individual who—

15 (A) does not qualify for coverage under a
16 Federal health care program (as defined in sec-
17 tion 1128B(f) of the Social Security Act (42
18 U.S.C. 1320a-7b(f))), the health program es-
19 tablished under chapter 89 of title 5, United
20 States Code, or a group health plan or group
21 health insurance coverage (as defined in section
22 2791 of the Public Health Service Act (42
23 U.S.C. 300gg-91)); and

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

4 (i) FUNDING.—To carry out this section, there are
5 authorized to be appropriated \$2,000,000 for each of fis-
6 cal years 2027 through 2032.