

Calendar No. 552

119TH CONGRESS
2D SESSION

S. 4189

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

IN THE SENATE OF THE UNITED STATES

MARCH 25, 2026

Mrs. SHAHEEN (for herself, Ms. COLLINS, Mr. WARNOCK, Mr. KENNEDY, Ms. ROSEN, Mr. TUBERVILLE, Mr. KING, Ms. MURKOWSKI, Mr. KELLY, Mr. GRASSLEY, Ms. BALDWIN, Mrs. BRITT, Mr. COONS, Mr. WICKER, Mr. KAINE, Mrs. CAPITO, Ms. BLUNT ROCHESTER, Mr. JUSTICE, Ms. ERNST, Mr. HICKENLOOPER, Mr. CRAMER, Ms. ALSOBROOKS, Mrs. HYDE-SMITH, Ms. CORTEZ MASTO, Mr. BANKS, Mr. BOOKER, Mr. MCCORMICK, Ms. SLOTKIN, and Mr. WARNER) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

AUGUST 7, 2026

Reported by Mr. CASSIDY, with an amendment

[Strike out all after the enacting clause and insert the part printed in italic]

A BILL

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

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

1 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

2 (a) **SHORT TITLE.**—This Act may be cited as the
 3 “Improving Needed Safeguards for Users of Lifesaving
 4 Insulin Now Act of 2026” or the “INSULIN Act of
 5 2026”.

6 (b) **TABLE OF CONTENTS.**—The table of contents for
 7 this Act is as follows:

Sec. 1. Short title; table of contents.

Sec. 2. Sense of Congress.

TITLE I—COMMERCIAL MARKET PATIENT PROTECTIONS

Sec. 101. Requirements with respect to cost-sharing for certain insulin prod-
 ucts.

Sec. 102. Application to retiree and certain small group plans.

Sec. 103. Administration.

**TITLE II—PHARMACY BENEFIT MANAGER TRANSPARENCY AND
 REBATE REFORM**

Sec. 201. Full rebate on insulin pass-through to plan.

**TITLE III—BIOSIMILAR BIOLOGICAL PRODUCT AND GENERIC
 DRUG COMPETITION AND AFFORDABILITY**

Sec. 301. Ensuring timely access to generics.

Sec. 302. Expediting competitive biosimilar competition.

Sec. 303. Insulin competition report.

**TITLE IV—PROGRAMS FOR PROVIDING AFFORDABLE INSULIN TO
 UNINSURED INDIVIDUALS**

Sec. 401. Pilot program for providing affordable insulin to uninsured individ-
 uals.

Sec. 402. GAO study on uninsured individuals who use insulin.

Sec. 403. Insulin resource center and hotline for uninsured individuals.

8 **SEC. 2. SENSE OF CONGRESS.**

9 It is the sense of Congress that Congress should
 10 enact subsequent legislation that provides for an offset for
 11 any costs to the Federal Government resulting from the
 12 enactment of this Act.

1 **TITLE I—COMMERCIAL MARKET**
 2 **PATIENT PROTECTIONS**

3 **SEC. 101. REQUIREMENTS WITH RESPECT TO COST-SHAR-**
 4 **ING FOR CERTAIN INSULIN PRODUCTS.**

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

8 **“SEC. 2799A–12. REQUIREMENTS WITH RESPECT TO COST-**
 9 **SHARING FOR CERTAIN INSULIN PRODUCTS.**

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

15 “(1) apply any deductible; or

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

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

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

22 “(i) \$35; or

23 “(ii) the amount equal to 25 percent
 24 of the negotiated price of the selected insu-
 25 lin product net of all price concessions re-

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 li-
censed and marketed, as selected by the group
health plan or health insurance issuer.

“(2) INSULIN.—The term ‘insulin’ means insu-
lin 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 prod-
ucts described in this section that are delivered by an out-
of-network provider, or precludes a plan or issuer that has

1 a network of providers from imposing higher cost-sharing
2 than the levels specified in subsection (a) for selected insu-
3 lin products described in this section that are delivered
4 by an out-of-network provider.

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

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

18 “(f) OTHER REQUIREMENTS.—A group health plan
19 or health insurance issuer offering group or individual
20 health insurance coverage shall not impose, directly or
21 through an entity providing pharmacy benefit manage-
22 ment services, any prior authorization or other medical
23 management requirement, or other similar conditions, on
24 selected insulin products, except as clinically justified for

1 safety reasons, to ensure reasonable quantity limits and
 2 as specified by the Secretary.”

3 (b) ~~NO EFFECT ON OTHER COST-SHARING.~~—Section
 4 1302(d)(2) of the Patient Protection and Affordable Care
 5 Act (42 U.S.C. 18022(d)(2)) is amended by adding at the
 6 end the following new subparagraph:

7 “(D) ~~SPECIAL RULE RELATING TO INSU-~~
 8 ~~LIN COVERAGE.~~—For plans years beginning on
 9 or after January 1, 2028, the exemption of cov-
 10 erage of selected insulin products (as defined in
 11 section 2799A–12(b) of the Public Health Serv-
 12 ice Act) from the application of any deductible
 13 pursuant to section 2799A–12(a)(1) of such
 14 Act, section 727(a)(1) of the Employee Retire-
 15 ment Income Security Act of 1974, or section
 16 9827(a)(1) of the Internal Revenue Code of
 17 1986 shall not be considered when determining
 18 the actuarial value of a qualified health plan
 19 under this subsection.”

20 (c) ~~COVERAGE OF CERTAIN INSULIN PRODUCTS~~
 21 ~~UNDER CATASTROPHIC PLANS.~~—Section 1302(c) of the
 22 Patient Protection and Affordable Care Act (42 U.S.C.
 23 18022(c)) is amended by adding at the end the following:

24 “(4) ~~COVERAGE OF CERTAIN INSULIN PROD-~~
 25 ~~UCTS.~~—

1 “(A) IN GENERAL.—Notwithstanding para-
 2 graph (1)(B)(i), for plan years beginning on or
 3 after January 1, 2027, a health plan described
 4 in paragraph (1) shall provide coverage of se-
 5 lected insulin products, in accordance with sec-
 6 tion ~~2799A–12~~ of the Public Health Service
 7 Act, before an enrolled individual has incurred,
 8 during the plan year, cost-sharing expenses in
 9 an amount equal to the annual limitation in ef-
 10 fect under subsection (c)(1) for the plan year.

11 “(B) TERMINOLOGY.—For purposes of
 12 subparagraph (A)—

13 “(i) the term ‘selected insulin prod-
 14 ucts’ has the meaning given such term in
 15 section ~~2799A–12(b)~~ of the Public Health
 16 Service Act; and

17 “(ii) the requirements of section
 18 ~~2799A–12~~ of such Act shall be applied by
 19 deeming each reference in such section to
 20 ‘individual health insurance coverage’ to be
 21 a reference to a plan described in para-
 22 graph (1).”.

23 (d) ERISA.—

24 (1) IN GENERAL.—Subpart B of part 7 of sub-
 25 title B of title I of the Employee Retirement Income

1 Security Act of 1974 (29 U.S.C. 1185 et seq.) is
2 amended by adding at the end the following:

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

5 “(a) IN GENERAL.—For plan years beginning on or
6 after January 1, 2027, a group health plan or health in-
7 surance issuer offering group health insurance coverage
8 shall provide coverage of selected insulin products, and
9 with respect to 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 or issuer,
22 including price concessions received by or
23 on behalf of third-party entities providing
24 services to the plan or issuer, such as

1 pharmacy benefit management services or
 2 third party administrators.

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 or health insurance issuer.~~

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 or issuer that has a network~~
 20 ~~of providers to provide benefits for selected insulin prod-~~
 21 ~~ucts described in this section that are delivered by an out-~~
 22 ~~of-network provider, or precludes a plan or issuer that has~~
 23 ~~a network of providers from imposing higher cost-sharing~~
 24 ~~than the levels specified in subsection (a) for selected insu-~~

1 lin products described in this section that are delivered
 2 by an out-of-network provider.

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

16 “(f) ~~OTHER REQUIREMENTS.~~—A group health plan
 17 or health insurance issuer offering group health insurance
 18 coverage shall not impose, directly or through an entity
 19 providing pharmacy benefit management services, any
 20 prior authorization or other medical management require-
 21 ment, or other similar conditions, on selected insulin prod-
 22 ucts, except as clinically justified for safety reasons, to en-
 23 sure reasonable quantity limits and as specified by the
 24 Secretary.”.

6 ~~(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:

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

16 ~~“(1) apply any deductible; or~~

17 “~~(2)~~ impose any cost-sharing requirements in

18 excess of, per 30-day supply—

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

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

23 ~~“(i) \$35; or~~

1 “(ii) the amount equal to 25 percent
 2 of the negotiated price of the selected insu-
 3 lin product net of all price concessions re-
 4 ceived by or on behalf of the plan, includ-
 5 ing price concessions received by or on be-
 6 half of third-party entities providing serv-
 7 ices to the plan, such as pharmacy benefit
 8 management services or third party admin-
 9 istrators.

10 “(b) DEFINITIONS.—In this section:

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

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

1 “(c) ~~OUT-OF-NETWORK PROVIDERS.~~—Nothing in
 2 this section requires a plan that has a network of providers
 3 to provide benefits for selected insulin products described
 4 in this section that are delivered by an out-of-network pro-
 5 vider, or precludes a plan that has a network of providers
 6 from imposing higher cost-sharing than the levels specified
 7 in subsection (a) for selected insulin products described
 8 in this section that are delivered by an out-of-network pro-
 9 vider.

10 “(d) ~~RULE OF CONSTRUCTION.~~—Subsection (a) shall
 11 not be construed to require coverage of, or prevent a group
 12 health plan from imposing cost-sharing other than the lev-
 13 els specified in subsection (a) on, insulin products that are
 14 not selected insulin products, to the extent that such cov-
 15 erage is not otherwise required and such cost-sharing is
 16 otherwise permitted under Federal and applicable State
 17 law.

18 “(e) ~~APPLICATION OF COST-SHARING TOWARDS~~
 19 ~~DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.~~—Any
 20 cost-sharing payments made pursuant to subsection (a)(2)
 21 shall be counted toward any deductible or out-of-pocket
 22 maximum that applies under the plan.

23 “(f) ~~OTHER REQUIREMENTS.~~—A group health plan
 24 shall not impose, directly or through an entity providing
 25 pharmacy benefit management services, any prior author-

1 ization or other medical management requirement, or
 2 other similar conditions, on selected insulin products, ex-
 3 cept as clinically justified for safety reasons, to ensure rea-
 4 sonable quantity limits and as specified by the Secretary.”.

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

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

9 **SEC. 102. APPLICATION TO RETIREE AND CERTAIN SMALL**
 10 **GROUP PLANS.**

11 (a) ERISA.—Section 732(a) of the Employee Retire-
 12 ment Income Security Act of 1974 (29 U.S.C. 1191a(a))
 13 is amended by striking “section 711” and inserting “sec-
 14 tions 711 and 727”.

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

17 (1) in section 9831(a), by adding at the end the
 18 following flush text:

19 “Paragraph (2) shall not apply to the requirements under
 20 sections 9811 and 9827.”; and

21 (2) in section 4980D(d)(1), by striking “section
 22 9811” and inserting “section 9811 or 9827”.

1 **SEC. 103. ADMINISTRATION.**

2 (a) **IMPLEMENTATION.**—Notwithstanding any other
3 provision of law, the Secretary of Health and Human
4 Services, the Secretary of Labor, and the Secretary of the
5 Treasury may implement the provisions of, including the
6 amendments made by, this title for plan years that begin
7 on or after January 1, 2027, and end not later than Janu-
8 ary 1, 2030, by subregulatory guidance, program instruc-
9 tion, or otherwise.

10 (b) **NON-APPLICATION OF THE PAPERWORK REDUC-**
11 **TION ACT.**—Chapter 35 of title 44, United States Code
12 (commonly referred to as the “Paperwork Reduction Act
13 of 1995”), shall not apply to the provisions of, including
14 the amendments made by, this title.

15 **TITLE II—PHARMACY BENEFIT**
16 **MANAGER TRANSPARENCY**
17 **AND REBATE REFORM**

18 **SEC. 201. FULL REBATE ON INSULIN PASS-THROUGH TO**
19 **PLAN.**

20 (a) **PHSA.**—Part D of title XXVII of the Public
21 Health Service Act (42 U.S.C. 300gg–111 et seq.), as
22 amended by section 101, is further amended by adding
23 at the end the following:

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

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

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

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

22 “(2) fully disclosed and enumerated to the
 23 group health plan sponsor; and

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

1 (b) ERISA.—

2 (1) IN GENERAL.—Subpart B of part 7 of sub-
 3 title B of title I of the Employee Retirement Income
 4 Security Act of 1974 (29 U.S.C. 1185 et seq.), as
 5 amended by section 101, is further amended by add-
 6 ing at the end the following:

7 **“SEC. 728. FULL REBATE ON INSULIN PASS-THROUGH TO**
 8 **PLAN.**

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

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

23 “(1) remitted to the group health plan in a
 24 timely fashion after the period for which such re-
 25 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 con-
9 tents in section 1 of the Employee Retirement In-
10 come Security Act of 1974 (29 U.S.C. 1001 et seq.),
11 as amended by section 101, is further amended by
12 inserting after the item relating to section 727 the
13 following:

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

14 (c) INTERNAL REVENUE CODE.—

15 (1) IN GENERAL.—Subchapter B of chapter
16 100 of the Internal Revenue Code of 1986, as
17 amended by section 101, is further amended by add-
18 ing at the end the following new section:

19 **“SEC. 9828. FULL REBATE ON INSULIN PASS-THROUGH TO**
20 **PLAN.**

21 “(a) IN GENERAL.—A pharmacy benefits manager,
22 a third-party administrator of a group health plan, or an
23 entity providing pharmacy benefits management services
24 under such health plan shall remit 100 percent of rebates,
25 fees, alternative discounts, and all other remuneration re-

1 received from a pharmaceutical manufacturer, distributor or
 2 any other third party, that are related to utilization of in-
 3 sulin under such health plan, to the group health plan.

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

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

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

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

17 (2) CLERICAL AMENDMENT.—The table of sec-
 18 tions for subchapter B of chapter 100 of such Code,
 19 as amended by section 101, is further amended by
 20 adding at the end the following new item:

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

1 **TITLE III—BIOSIMILAR BIOLOGI-**
 2 **CAL PRODUCT AND GENERIC**
 3 **DRUG COMPETITION AND AF-**
 4 **FORDABILITY**

5 **SEC. 301. ENSURING TIMELY ACCESS TO GENERICS.**

6 Section 505(q) of the Federal Food, Drug, and Cos-
 7 metic Act (21 U.S.C. 355(q)) is amended—

8 (1) in paragraph (1)—

9 (A) in subparagraph (A)(i), by inserting “,
 10 10.31,” after “10.30”;

11 (B) in subparagraph (E)—

12 (i) by striking “application and” and
 13 inserting “application or”;

14 (ii) by striking “If the Secretary” and
 15 inserting the following:

16 “(i) IN GENERAL.—If the Secretary”;
 17 and

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

20 “(ii) PRIMARY PURPOSE OF DELAY-
 21 ING.—

22 “(I) IN GENERAL.—In deter-
 23 mining whether a petition was sub-
 24 mitted with the primary purpose of

1 delaying an application, the Secretary
2 may consider the following factors:

3 “(aa) Whether the petition
4 was submitted in accordance with
5 paragraph (2)(B), based on when
6 the petitioner knew or reasonably
7 should have known the relevant
8 information relied upon to form
9 the basis of such petition.

10 “(bb) Whether the petitioner
11 has submitted multiple or serial
12 petitions or supplements to peti-
13 tions raising issues that reason-
14 ably could have been known to
15 the petitioner at the time of sub-
16 mission of the earlier petition or
17 petitions.

18 “(cc) Whether the petition
19 was submitted close in time to a
20 known, first date upon which an
21 application under subsection
22 (b)(2) or (j) of this section or
23 section 351(k) of the Public
24 Health Service Act could be ap-
25 proved.

1 “(dd) Whether the petition
2 was submitted without relevant
3 data or information in support of
4 the scientific positions forming
5 the basis of such petition.

6 “(ee) Whether the petition
7 raises the same or substantially
8 similar issues as a prior petition
9 to which the Secretary has re-
10 sponded substantively already, in-
11 cluding if the subsequent submis-
12 sion follows such response from
13 the Secretary closely in time.

14 “(ff) Whether the petition
15 requests changing the applicable
16 standards that other applicants
17 are required to meet, including
18 requesting testing, data, or label-
19 ing standards that are more on-
20 erous or rigorous than the stand-
21 ards the Secretary has deter-
22 mined to be applicable to the list-
23 ed drug, reference product, or pe-
24 titioner’s version of the same
25 drug.

1 “(gg) The petitioner’s record
 2 of submitting petitions to the
 3 Food and Drug Administration
 4 that have been determined by the
 5 Secretary to have been submitted
 6 with the primary purpose of
 7 delay.

8 “(hh) Other relevant and
 9 appropriate factors, which the
 10 Secretary shall describe in guid-
 11 ance.

12 “(H) GUIDANCE.—The Secretary
 13 may issue or update guidance, as ap-
 14 propriate, to describe factors the Sec-
 15 retary considers in accordance with
 16 subclause (I).”;

17 (C) by adding at the end the following:

18 “(iii) REFERRAL TO THE FEDERAL
 19 TRADE COMMISSION.—The Secretary shall
 20 establish procedures for referring to the
 21 Federal Trade Commission any petition or
 22 supplement to a petition that the Secretary
 23 determines was submitted with the primary
 24 purpose of delaying approval of an applica-

tion. Such procedures shall include notification to the petitioner by the Secretary.”;

(D) by striking subparagraph (F);

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

(F) 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

1 basis of the relief requested in any civil action
2 described in the previous sentence.

3 “(B) ~~TIMELY SUBMISSION OF CITIZEN PE-~~
4 ~~TITION.~~—A petition and any supplement to a
5 petition shall be submitted within 60 days after
6 the person knew, or reasonably should have
7 known, the information that forms the basis of
8 the request made in the petition or supple-
9 ment.”;

10 (C) in subparagraph (C), as so redesign-
11 nated—

12 (i) in the heading, by striking “WITH-
13 IN 150 DAYS”;

14 (ii) in clause (i), by striking “during
15 the 150-day period referred to in para-
16 graph (1)(F),”;

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

19 “(ii) on or after the date that is 151
20 days after the date of submission of the
21 petition, the Secretary approves or has ap-
22 proved the application that is the subject
23 of the petition without having made such a
24 final decision.”;

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

3 ~~“(D) DISMISSAL OF CERTAIN CIVIL AC-~~
 4 ~~TIONS.—~~

5 ~~“(i) PETITION.—~~If a person files a
 6 civil action against the Secretary in which
 7 a person seeks to set aside, delay, rescind,
 8 withdraw, or prevent submission, review, or
 9 approval of an application submitted under
 10 subsection ~~(b)(2)~~ or ~~(j)~~ of this section or
 11 section 351(k) of the Public Health Service
 12 Act without complying with the require-
 13 ments of subparagraph ~~(A)~~, the court shall
 14 dismiss without prejudice the action for
 15 failure to exhaust administrative remedies.

16 ~~“(ii) TIMELINESS.—~~If a person files a
 17 civil action against the Secretary in which
 18 a person seeks to set aside, delay, rescind,
 19 withdraw, or prevent submission, review, or
 20 approval of an application submitted under
 21 subsection ~~(b)(2)~~ or ~~(j)~~ of this section or
 22 section 351(k) of the Public Health Service
 23 Act without complying with the require-
 24 ments 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)”;

(3) in paragraph (4)—

(A) by striking “EXCEPTIONS” 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. 302. EXPEDITING COMPETITIVE 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 COMPETITIVE BIOSIMILAR COMPETITION.—

“(A) IN GENERAL.—The Secretary may, at the request of the sponsor of an application under this subsection for a biosimilar biological product that is designated as a competitive biosimilar therapy pursuant to subsection (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

1 as a competitive biosimilar therapy. A re-
2 quest for such designation may be made
3 concurrently with, or at any time prior to,
4 the submission of a biosimilar biological
5 product license application under this sub-
6 section.

7 “(ii) CRITERIA.—A biological product
8 is eligible for designation as a competitive
9 biosimilar therapy under this paragraph if
10 the Secretary determines that there is in-
11 adequate biosimilar competition.

12 “(iii) DESIGNATION.—Not later than
13 60 calendar days after the receipt of a re-
14 quest under clause (i), the Secretary
15 may—

16 “(I) determine whether the bio-
17 similar biological product that is the
18 subject of the request meets the cri-
19 teria described in clause (ii); and

20 “(II) if the Secretary finds that
21 such product meets such criteria, des-
22 ignate the biosimilar biological prod-
23 uct as a competitive biosimilar ther-
24 apy.

1 “(C) ACTIONS.—In expediting the develop-
2 ment and review of an application under sub-
3 paragraph (A), the Secretary may, as requested
4 by the applicant, take actions including the fol-
5 lowing:

6 “(i) Hold meetings with the sponsor
7 and the review team throughout the devel-
8 opment of the biosimilar biological product
9 prior to submission of the application
10 under this subsection.

11 “(ii) Provide timely advice to, and
12 interactive communication with, the spon-
13 sor regarding the development of the drug
14 to ensure that the development program to
15 gather the data necessary for approval is
16 as efficient as practicable.

17 “(iii) Involve senior managers and ex-
18 perienced review staff, as appropriate, in a
19 collaborative, coordinated review of such
20 application, including with respect to bio-
21 logical product-device combination prod-
22 ucts and other complex products.

23 “(iv) Assign a cross-disciplinary
24 project lead—

1 “(I) to facilitate an efficient re-
2 view of the development program and
3 application, including manufacturing
4 inspections; and

5 “(II) to serve as a scientific liai-
6 son between the review team and the
7 applicant.

8 “(D) INSPECTIONS.—With respect to an
9 application described in subparagraph (A), in
10 the case of an inspection report that finds ap-
11 proval of such biological product is dependent
12 upon remediation of a facility, if the applicant
13 attests that necessary changes have been made
14 to the facility, the Secretary shall expedite rein-
15 spection of such facility, including establishing
16 a set timeline to reinspect the facility or make
17 a determination about the response of the appli-
18 cant and whether to approve the application.

19 “(E) REPORTING REQUIREMENT.—Not
20 later than 1 year after the date of licensure
21 under this subsection with respect to a bio-
22 similar biological product for which the develop-
23 ment and review is expedited under this para-
24 graph, the holder of the license of such bio-
25 similar biological product shall report to the

1 Secretary on whether the biosimilar biological
 2 product has been marketed in interstate com-
 3 merce since the date of such licensure.

4 “(F) INADEQUATE BIOSIMILAR COMPETI-
 5 TION.—In this paragraph, the term ‘inadequate
 6 biosimilar competition’ means, with respect to a
 7 biological product, there are fewer than 3 li-
 8 censed biological products on the list published
 9 under paragraph (9)(A) (not including biologi-
 10 cal products on the discontinued section of such
 11 list) that are biosimilar biological products with
 12 the same reference product.”.

13 **SEC. 303. INSULIN COMPETITION REPORT.**

14 Not later than 1 year after the date of the enactment
 15 of this Act, the Secretary of Health and Human Services,
 16 in collaboration with the Administrator for the Centers for
 17 Medicare & Medicaid Services and the Commissioner of
 18 Food and Drugs, shall—

19 (1) complete a study to determine the extent of,
 20 and causes of, delays in getting insulin products to
 21 market, and the market dynamics and extent bio-
 22 similar biological product development and competi-
 23 tion could increase, or is increasing, the number of
 24 biological products approved and available to pa-
 25 tients, including by examining barriers to—

1 (A) placement of biosimilar biological prod-
 2 ucts on health insurance formularies;

3 (B) market entry of insulin product in the
 4 United States, as compared to other highly de-
 5 veloped nations; and

6 (C) patient and provider education around
 7 biosimilar biological products; and

8 (2) submit a report to Congress that describes
 9 the results of the study conducted pursuant to para-
 10 graph (1) and recommended policy solutions.

11 **TITLE IV—PROGRAMS FOR PRO-**
 12 **VIDING AFFORDABLE INSU-**
 13 **LIN TO UNINSURED INDIVID-**
 14 **UALS**

15 **SEC. 401. 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

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. 402. 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;

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 401.

8 **SEC. 403. 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 (e);

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 (c), 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 (c) 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(1)(2) of the Social Security Act (42 U.S.C.
 4 1396d(1)(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.~~

7 **SECTION 1. SHORT TITLE.**

8 *This Act may be cited as the “Improving Needed Safe-*
 9 *guards for Users of Lifesaving Insulin Now Act of 2026”*
 10 *or the “INSULIN Act of 2026”.*

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

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

16 ~~**“SEC. 2729A. REQUIREMENTS WITH RESPECT TO COST-**~~
 17 ~~**SHARING FOR CERTAIN INSULIN PRODUCTS.**~~

18 ~~“(a) IN GENERAL.—For plan years beginning on or~~
 19 ~~after January 1, 2028, a group health plan or health insur-~~
 20 ~~ance issuer offering group or individual health insurance~~
 21 ~~coverage shall provide coverage of selected insulin products,~~
 22 ~~and with respect to such products, shall not—~~

23 ~~“(1) apply any deductible; or~~

24 ~~“(2) impose any cost-sharing requirements in ex-~~
 25 ~~cess of, per 30-day supply—~~

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

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

5 “(i) \$35; or

6 “(ii) the amount equal to 25 percent of
7 the negotiated price of the selected insulin
8 product net of all price concessions received
9 by or on behalf of the plan or issuer, includ-
10 ing price concessions received by or on be-
11 half of third-party entities providing serv-
12 ices to the plan or issuer, such as pharmacy
13 benefit management services or third party
14 administrators.

15 “(b) *DEFINITIONS.*—In this section:

16 “(1) *INSULIN.*—The term ‘insulin’ means insulin
17 that is licensed under subsection (a) or (k) of section
18 351, including insulin deemed to be licensed under
19 section 351 pursuant to section 7002(e)(4) of the Bio-
20 logics Price Competition and Innovation Act of 2009,
21 and continues to be marketed pursuant to such licen-
22 sure.

23 “(2) *SELECTED INSULIN PRODUCTS.*—The term
24 ‘selected insulin products’ means, for any plan year
25 beginning on or after January 1, 2028, at least one

1 of each dosage form and delivery device (such as vial,
 2 pen, inhaler dosage forms, or such other delivery de-
 3 vices approved by the Secretary) of each different type
 4 (such as rapid-acting, short-acting, intermediate-act-
 5 ing, long-acting, and pre-mixed) of insulin, when
 6 such form is licensed and marketed, as selected by the
 7 group health plan or health insurance issuer.

8 “(c) *OUT-OF-NETWORK PROVIDERS.*—Nothing in this
 9 section requires a plan or issuer that has a network of pro-
 10 viders to provide benefits for selected insulin products de-
 11 scribed in this section that are delivered by an out-of-net-
 12 work provider, or precludes a plan or issuer that has a net-
 13 work of providers from imposing higher cost-sharing than
 14 the levels specified in subsection (a) for selected insulin
 15 products described in this section that are delivered by an
 16 out-of-network provider if permitted under applicable law.

17 “(d) *RULES OF CONSTRUCTION.*—Subsection (a) shall
 18 not be construed to—

19 “(1) require coverage of, or prevent a group
 20 health plan or health insurance issuer from imposing
 21 cost-sharing other than the levels specified in sub-
 22 section (a) on, insulin that is not a selected insulin
 23 product, to the extent that such coverage is not other-
 24 wise required and such cost-sharing is otherwise per-
 25 mitted under Federal and applicable State law; or

1 “(2) permit a group health plan or health insur-
 2 ance issuer to pay any amount in excess of the
 3 amount specified under section (a)(2) to an entity
 4 providing pharmaceutical benefit management serv-
 5 ices, a provider, or a pharmaceutical manufacturer
 6 with respect to the provision of selected insulin prod-
 7 ucts.

8 “(e) *APPLICATION OF PATIENT PROTECTIONS.*—The
 9 provisions of this title shall apply to selected insulin prod-
 10 uct benefits described in subsection (a) as though such bene-
 11 fits were required to be provided under section 2707(a).

12 “(f) *OTHER REQUIREMENTS.*—A group health plan or
 13 health insurance issuer offering group or individual health
 14 insurance coverage shall not impose, directly or through an
 15 entity providing services to the plan or coverage, any prior
 16 authorization or medical management requirement, or other
 17 similar conditions, on selected insulin products, except as
 18 clinically justified for safety reasons, to ensure reasonable
 19 quantity limits, and 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 INSULIN*
 25 *COVERAGE.*—For plan years beginning on or

1 *after January 1, 2028, the exemption of coverage*
 2 *of selected insulin products (as defined in section*
 3 *2729A of the Public Health Service Act) from the*
 4 *application of any deductible pursuant to section*
 5 *2729(a)(1) of such Act shall not be treated as in-*
 6 *creasing the actuarial value of a plan when de-*
 7 *termining the actuarial value of a qualified*
 8 *health plan under this subsection.”.*

9 (c) *COVERAGE OF CERTAIN INSULIN PRODUCTS*

10 *UNDER CATASTROPHIC PLANS.—Section 1302(e) of the Pa-*
 11 *tient Protection and Affordable Care Act (42 U.S.C.*
 12 *18022(e)) is amended by adding at the end the following:*

13 “(4) *COVERAGE OF CERTAIN INSULIN PROD-*
 14 *UCTS.—*

15 “(A) *IN GENERAL.—Notwithstanding para-*
 16 *graph (1)(B)(i), for plan years beginning on or*
 17 *after January 1, 2028, a health plan described*
 18 *in paragraph (1) shall provide coverage of se-*
 19 *lected insulin products, in accordance with sec-*
 20 *tion 2729A of the Public Health Service Act, be-*
 21 *fore an enrolled individual has incurred, during*
 22 *the plan year, cost-sharing expenses in an*
 23 *amount equal to the annual limitation in effect*
 24 *under subsection (c)(1) for the plan year.*

1 “(B) *TERMINOLOGY.*—For purposes of sub-
2 paragraph (A)—

3 “(i) the term ‘selected insulin products’
4 has the meaning given such term in section
5 2729A(b) of the Public Health Service Act;
6 and

7 “(ii) the requirements of section 2729A
8 of such Act shall be applied by deeming
9 each reference in such section to ‘individual
10 health insurance coverage’ to be a reference
11 to a plan described in paragraph (1).”.

12 (d) *CONFORMING AMENDMENTS.*—

13 (1) *ERISA.*—Section 715(a)(1) of the Employee
14 Retirement Income Security Act of 1974 (29 U.S.C.
15 1185d(a)(1)) is amended by inserting “and the IN-
16 SULIN Act of 2026” after “Affordable Care Act”.

17 (2) *IRC.*—Section 9815(a)(1) of the Internal
18 Revenue Code of 1986 is amended by inserting “and
19 the INSULIN Act of 2026” after “Affordable Care
20 Act”.

21 **SEC. 3. ADMINISTRATION.**

22 (a) *IMPLEMENTATION.*—Notwithstanding any other
23 provision of law, the Secretary of Health and Human Serv-
24 ices, the Secretary of Labor, and the Secretary of the Treas-
25 ury may implement the provisions of, including the amend-

1 ments made by, section 2 for plan years that begin on or
 2 after January 1, 2028, and end not later than January
 3 1, 2030, by subregulatory guidance, program instruction,
 4 or otherwise.

5 (b) *NON-APPLICATION OF THE PAPERWORK REDUC-*
 6 *TION ACT.*—Chapter 35 of title 44, United States Code
 7 (commonly referred to as the “Paperwork Reduction Act of
 8 1995”), shall not apply to the provisions of, including the
 9 amendments made by, section 2.

10 **SEC. 4. GAO STUDY ON UNINSURED INDIVIDUALS WHO USE**
 11 **INSULIN.**

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

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

21 (2) *any identifiable potential reasons for unin-*
 22 *sured status;*

23 (3) *demographic characteristics of such individ-*
 24 *uals, such as race and ethnicity; and*

25 (4) *income level of such individuals.*

1 **SEC. 5. ENSURING TIMELY ACCESS TO GENERICS.**

2 *Section 505(q) of the Federal Food, Drug, and Cos-*
 3 *metic Act (21 U.S.C. 355(q)) is amended—*

4 *(1) in paragraph (1)—*

5 *(A) in subparagraph (A)(i), by inserting “,*
 6 *10.31,” after “10.30”;*

7 *(B) in subparagraph (E)—*

8 *(i) by striking “application and” and*
 9 *inserting “application or”;*

10 *(ii) by striking “If the Secretary” and*
 11 *inserting the following:*

12 *“(i) IN GENERAL.—If the Secretary”;*
 13 *and*

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

16 *“(ii) PRIMARY PURPOSE OF DELAY-*
 17 *ING.—*

18 *“(I) IN GENERAL.—In deter-*
 19 *mining whether a petition was sub-*
 20 *mitted with the primary purpose of de-*
 21 *laying an application, the Secretary*
 22 *may consider the following factors:*

23 *“(aa) Whether the petition*
 24 *was submitted in accordance with*
 25 *paragraph (2)(B), based on when*
 26 *the petitioner knew the relevant*

1 *information relied upon to form*
2 *the basis of such petition.*

3 “(bb) *When the petition was*
4 *submitted in relation to when the*
5 *petitioner reasonably should have*
6 *known the relevant information*
7 *relied upon to form the basis of*
8 *such petition.*

9 “(cc) *Whether the petitioner*
10 *has submitted multiple or serial*
11 *petitions or supplements to peti-*
12 *tions raising issues that reason-*
13 *ably could have been known to the*
14 *petitioner at the time of submis-*
15 *sion of the earlier petition or peti-*
16 *tions.*

17 “(dd) *Whether the petition*
18 *was submitted close in time to a*
19 *known, first date upon which an*
20 *application under subsection*
21 *(b)(2) or (j) of this section or sec-*
22 *tion 351(k) of the Public Health*
23 *Service Act could be approved.*

24 “(ee) *Whether the petition*
25 *was submitted without relevant*

1 data or information in support of
2 the scientific positions forming the
3 basis of such petition.

4 “(ff) Whether the petition
5 raises the same or substantially
6 similar issues as a prior petition
7 to which the Secretary has re-
8 sponded substantively already, in-
9 cluding if the subsequent submis-
10 sion follows such response from
11 the Secretary closely in time.

12 “(gg) Whether the petition
13 requests changing the applicable
14 standards that other applicants
15 are required to meet, including re-
16 questing testing, data, or labeling
17 standards that are more onerous
18 or rigorous than the standards the
19 Secretary has determined to be
20 applicable to the listed drug, ref-
21 erence product, or petitioner’s
22 version of the same drug.

23 “(hh) The petitioner’s record
24 of submitting petitions to the
25 Food and Drug Administration

1 that have been determined by the
 2 Secretary to have been submitted
 3 with the primary purpose of
 4 delay.

5 “(ii) Other relevant and ap-
 6 propriate factors, which the Sec-
 7 retary shall describe in guidance.

8 “(II) GUIDANCE.—The Secretary
 9 may issue or update guidance, as ap-
 10 propriate, to describe factors the Sec-
 11 retary considers in accordance with
 12 subclause (I).”;

13 (C) by striking subparagraph (F);

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

17 (E) in subparagraph (G), as so redesign-
 18 ated, by striking “submission of this petition”
 19 and inserting “submission of this document”;

20 (2) in paragraph (2)—

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

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

1 “(A) *IN GENERAL.*—A person shall submit a
 2 petition to the Secretary under paragraph (1)
 3 before filing a civil action in which the person
 4 seeks to set aside, delay, rescind, withdraw, or
 5 prevent submission, review, or approval of an
 6 application submitted under subsection (b)(2) or
 7 (j) of this section or section 351(k) of the Public
 8 Health Service Act. Such petition and any sup-
 9 plement to such a petition shall describe all in-
 10 formation and arguments that form the basis of
 11 the relief requested in any civil action described
 12 in the previous sentence.

13 “(B) *TIMELY SUBMISSION OF CITIZEN PETI-*
 14 *TION.*—A petition and any supplement to a peti-
 15 tion shall be submitted within 180 days after the
 16 person knew the information that forms the basis
 17 of the request made in the petition or supple-
 18 ment.”;

19 (C) in subparagraph (C), as so redesign-
 20 nated—

21 (i) in the heading, by striking “*WITHIN*
 22 *150 DAYS*”;

23 (ii) in clause (i), by striking “*during*
 24 *the 150-day period referred to in paragraph*
 25 *(1)(F)*,”; and

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

3 “(ii) on or after the date that is 151
4 days after the date of submission of the peti-
5 tion, the Secretary approves or has ap-
6 proved the application that is the subject of
7 the petition without having made such a
8 final decision.”;

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

11 “(D) DISMISSAL OF CERTAIN CIVIL AC-
12 TIONS.—

13 “(i) PETITION.—If a person files a
14 civil action against the Secretary in which
15 a person seeks to set aside, delay, rescind,
16 withdraw, or prevent submission, review, or
17 approval of an application submitted under
18 subsection (b)(2) or (j) of this section or sec-
19 tion 351(k) of the Public Health Service Act
20 without complying with the requirements of
21 subparagraph (A), the court shall dismiss
22 without prejudice the action for failure to
23 exhaust administrative remedies.

24 “(ii) TIMELINESS.—If a person files a
25 civil action against the Secretary in which

1 a person seeks to set aside, delay, rescind,
 2 withdraw, or prevent submission, review, or
 3 approval of an application submitted under
 4 subsection (b)(2) or (j) of this section or sec-
 5 tion 351(k) of the Public Health Service Act
 6 without complying with the requirements of
 7 subparagraph (B), the court shall dismiss
 8 with prejudice the action for failure to time-
 9 ly file a petition.

10 “(iii) *FINAL RESPONSE*.—If a civil ac-
 11 tion is filed against the Secretary with re-
 12 spect to any issue raised in a petition time-
 13 ly filed under paragraph (1) in which the
 14 petitioner requests that the Secretary take
 15 any form of action that could, if taken, set
 16 aside, delay, rescind, withdraw, or prevent
 17 submission, review, or approval of an appli-
 18 cation submitted under subsection (b)(2) or
 19 (j) of this section or section 351(k) of the
 20 Public Health Service Act before the Sec-
 21 retary has taken final agency action on the
 22 petition within the meaning of subpara-
 23 graph (C), the court shall dismiss without
 24 prejudice the action for failure to exhaust
 25 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 develop-

ment 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

1 “(II) if the Secretary finds that
 2 such product meets such criteria, des-
 3 ignate the biosimilar biological product
 4 as a competitive biosimilar biological
 5 product.

6 “(C) INADEQUATE BIOSIMILAR COMPETI-
 7 TION.—In this paragraph, the term ‘inadequate
 8 biosimilar competition’ means that, with respect
 9 to a biological product licensed under subsection
 10 (a)—

11 “(i) on the list published under para-
 12 graph (9)(A) (not including biological prod-
 13 ucts on the discontinued section of such
 14 list), there are fewer than 3 biological prod-
 15 ucts licensed under this subsection pursuant
 16 to an application that uses such biological
 17 product licensed under subsection (a) as a
 18 reference product; and

19 “(ii) not less than 3 years have passed
 20 since the expiration of all exclusivity peri-
 21 ods applicable to such biological product li-
 22 censed under subsection (a), or applicable to
 23 a biosimilar biological product licensed
 24 under this subsection using such biological
 25 product licensed under subsection (a) as a

1 reference product, including any exclusivity
2 periods under—

3 “(I) paragraph (6);

4 “(II) paragraph (7)(A);

5 “(III) section 527 of the Federal
6 Food, Drug, and Cosmetic Act; and

7 “(IV) subsection (m).”.

8 **SEC. 7. PILOT PROGRAM FOR PROVIDING AFFORDABLE IN-**
9 **SULIN TO UNINSURED INDIVIDUALS.**

10 Part P of title III of the Public Health Service Act
11 (42 U.S.C. 280g et seq.) is amended by adding at the end
12 the following:

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

15 “(a) *IN GENERAL.*—The Secretary shall conduct a 5-
16 year pilot program under which the Secretary awards
17 grants to 10 States for purposes of providing affordable in-
18 sulin to uninsured individuals.

19 “(b) *AWARDS.*—The Secretary shall award grants
20 under this section to 10 States that—

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

1 “(2) *have high rates of uninsured individuals*
2 *and individuals diagnosed with diabetes, which may*
3 *include high rates of newly diagnosed diabetes.*

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

7 “(1) *To assist in the purchase or dispensing of*
8 *insulin, through Federally-qualified health centers*
9 *and retail community pharmacies, for uninsured in-*
10 *dividuals.*

11 “(2) *To provide assistance to individuals in pro-*
12 *grams under which drug manufacturers provide fi-*
13 *nancial or medication assistance to low-income indi-*
14 *viduals, in order to assist such individuals in obtain-*
15 *ing insulin.*

16 “(3) *To support Federally-qualified health cen-*
17 *ters in establishing new, or maintaining or expand-*
18 *ing existing, on-site pharmacies owned and operated*
19 *by the health center that provide low-cost insulin to*
20 *patients, and to support retail community phar-*
21 *macies in providing low-cost insulin to patients.*

22 “(4) *To engage in other activities to assist unin-*
23 *surbed individuals in obtaining insulin, as the Sec-*
24 *retary determines appropriate.*

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

4 “(1) *provide for a minimum amount that will be*
 5 *provided to each State; and*

6 “(2) *take into account the rates of individuals*
 7 *with type 1 or type 2, insulin-dependent diabetes and*
 8 *the number of uninsured individuals in each State for*
 9 *purposes of determining any additional amounts pro-*
 10 *vided to a State.*

11 “(e) *ACCOUNTABILITY AND OVERSIGHT.*—*A State re-*
 12 *ceiving a grant under this section shall, not later than 1*
 13 *year after receiving the grant, submit a report to the Sec-*
 14 *retary that includes—*

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

19 “(2) *the number of individuals served through*
 20 *the grant.*

21 “(f) *DEFINITIONS.*—*In this section:*

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

1 “(2) *FEDERALLY-QUALIFIED HEALTH CENTER.*—
 2 *The term ‘Federally-qualified health center’ has the*
 3 *meaning given such term in section 1905(l)(2) of the*
 4 *Social Security Act.*

5 “(3) *INSULIN.*—*The term ‘insulin’ means insulin*
 6 *that is licensed under subsection (a) or (k) of section*
 7 *351 and continues to be marketed under such section.*

8 “(4) *RETAIL COMMUNITY PHARMACY.*—*The term*
 9 *‘retail community pharmacy’ has the meaning given*
 10 *such term in section 1927(k)(10) of the Social Secu-*
 11 *rity Act.*

12 “(5) *UNINSURED INDIVIDUAL.*—*The term ‘unin-*
 13 *sured individual’ means an individual who—*

14 “(A) *is a citizen of the United States or a*
 15 *qualified alien (as defined in section 431(b) of*
 16 *the Personal Responsibility and Work Oppor-*
 17 *tunity Reconciliation Act of 1996); and*

18 “(B) *is not enrolled in coverage under a*
 19 *Federal health care program (as defined in sec-*
 20 *tion 1128B(f) of the Social Security Act), the*
 21 *health program established under chapter 89 of*
 22 *title 5, United States Code, or a group health*
 23 *plan or group health insurance coverage (as de-*
 24 *finied in section 2791).*

1 “(g) *AUTHORIZATION OF APPROPRIATIONS.*—To carry
 2 out this section, there is authorized to be appropriated
 3 \$100,000,000 for fiscal year 2027, to remain available until
 4 expended.”.

5 **SEC. 8. INSULIN RESOURCE CENTER AND HOTLINE FOR UN-**
 6 **INSURED INDIVIDUALS.**

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

11 (1) *establishing and maintaining a resource cen-*
 12 *ter of assistance programs offered by manufactures or*
 13 *other entities that are available to uninsured individ-*
 14 *uals seeking affordable insulin; and*

15 (2) *conducting the public education activities de-*
 16 *scribed in subsection (c)(7).*

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

19 (1) *be a trade, industry, or professional associa-*
 20 *tion, community- and consumer-focused nonprofit en-*
 21 *tity, or other entity, as determined by the Secretary,*
 22 *that—*

23 (A) *is capable of carrying out the duties de-*
 24 *scribed in subsection (c);*

1 (B) meets the standards described in sub-
2 section (e); and

3 (C) provides information consistent with the
4 standards developed under subsection (e); and

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

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

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

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

23 (1) distribute fair and impartial information
24 concerning eligibility for manufacturer, foundational,

1 *and other assistance programs available to patients*
2 *seeking affordable insulin;*

3 *(2) facilitate enrollment in manufacturer assist-*
4 *ance programs or other assistance programs for unin-*
5 *sured individuals;*

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

9 *(A) a link to Federally-qualified health cen-*
10 *ters and other providers, by ZIP Code;*

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

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

15 *(4) provide information in a manner that is cul-*
16 *turally and linguistically appropriate;*

17 *(5) establish a hotline through which individuals*
18 *may reach experts with questions about access to in-*
19 *sulin, and that—*

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

21 *(B) provides voice and text support; and*

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

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

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

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

12 (B) *working with State and local health de-*
13 *partments to target the programs carried out*
14 *using the grant to underserved communities.*

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

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

20 (2) *publicize such resource center on the website*
21 *of the Department of Health and Human Services*
22 *and across Federal agencies, as the Secretary deter-*
23 *mines appropriate; and*

24 (3) *ensure that such resource center meets the*
25 *standards under subsection (e), and withdraw the*

1 *grant and make an award to a different eligible enti-*
 2 *ty in the case that an eligible entity fails to meet such*
 3 *standards.*

4 *(e) STANDARDS.—The Secretary shall establish stand-*
 5 *ards for the resource center under this section, including*
 6 *provisions to ensure that the entity receiving a grant under*
 7 *this section is qualified to engage in the activities described*
 8 *in this section and to avoid conflicts of interest. Under such*
 9 *standards, such entity—*

10 *(1) shall not—*

11 *(A) be a manufacturer of insulin products;*

12 *or*

13 *(B) receive any consideration directly or in-*
 14 *directly from any manufacturer of insulin prod-*
 15 *ucts in connection with the enrollment of any in-*
 16 *dividuals in an assistance program; and*

17 *(2) shall provide information that is fair, accu-*
 18 *rate, and impartial.*

19 *(f) DATA COLLECTION AND EVALUATIONS.—The Sec-*
 20 *retary may collect data and conduct evaluations with re-*
 21 *spect to the services provided by the resource center de-*
 22 *scribed in this section for purposes of assessing the extent*
 23 *to which the provision of the services—*

24 *(1) reduces out of pocket insulin costs for unin-*
 25 *sured individuals;*

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

4 (3) *improves utilization of the resources de-*
 5 *scribed in paragraph (2) by uninsured individuals.*

6 (g) *REPORTS TO CONGRESS.—The Secretary shall sub-*
 7 *mit to the Committee on Health, Education, Labor, and*
 8 *Pensions and the Committee on Appropriations of the Sen-*
 9 *ate and the Committee on Energy and Commerce and the*
 10 *Committee on Appropriations of the House of Representa-*
 11 *tives, and make publicly available, annual reports on the*
 12 *activities carried out under this section, including any*
 13 *changes in the availability or scope of assistance programs*
 14 *offered by insulin manufacturers and information about the*
 15 *number of individuals who use the resource center, includ-*
 16 *ing the website or hotline.*

17 (h) *DEFINITIONS.—In this section—*

18 (1) *the term “assistance program” means a pro-*
 19 *gram to assist patients in obtaining a drug at a re-*
 20 *duced cost, and includes third-party payments, finan-*
 21 *cial assistance, discounts, product vouchers, and other*
 22 *reductions in out-of-pocket expenses;*

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

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

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

9 (5) the term “uninsured individual” means an
 10 individual who is not enrolled in coverage under a
 11 Federal health care program (as defined in section
 12 1128B(f) of the Social Security Act (42 U.S.C.
 13 1320a-7b(f))), the health program established under
 14 chapter 89 of title 5, United States Code, or a group
 15 health plan or group health insurance coverage (as
 16 defined in section 2791 of the Public Health Service
 17 Act (42 U.S.C. 300gg-91)).

18 (i) *FUNDING.*—To carry out this section, there are au-
 19 thorized to be appropriated \$2,000,000 for each of fiscal
 20 years 2027 through 2032.

Calendar No. 552

119TH CONGRESS
2^D Session

S. 4189

A BILL

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

AUGUST 7, 2026

Reported with an amendment