

119TH CONGRESS
2D SESSION

S. _____

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

Mrs. SHAHEEN (for herself, Ms. COLLINS, Mr. WARNOCK, and Mr. KENNEDY) introduced the following bill; which was read twice and referred to the Committee on _____

A BILL

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

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

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Improving Needed Safeguards for Users of Lifesaving
6 Insulin Now Act of 2026” or the “INSULIN Act of
7 2026”.

8 (b) TABLE OF CONTENTS.—The table of contents for
9 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 products.
- 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 individuals.
- Sec. 402. GAO study on uninsured individuals who use insulin.
- Sec. 403. Insulin resource center and hotline for uninsured individuals.

1 SEC. 2. SENSE OF CONGRESS.

2 It is the sense of Congress that Congress should
 3 enact subsequent legislation that provides for an offset for
 4 any costs to the Federal Government resulting from the
 5 enactment of this Act.

6 **TITLE I—COMMERCIAL MARKET**
 7 **PATIENT PROTECTIONS**

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

10 (a) IN GENERAL.—Part D of title XXVII of the Pub-
 11 lic Health Service Act (42 U.S.C. 300gg–111 et seq.) is
 12 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 insu-
17 lin products 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. 102. 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 “section 711” and inserting “sec-
8 tions 711 and 727”.

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

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

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

15 (2) in section 4980D(d)(1), by striking “section
16 9811” and inserting “section 9811 or 9827”.

17 **SEC. 103. ADMINISTRATION.**

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

1 ary 1, 2030, by subregulatory guidance, program instruc-
2 tion, or otherwise.

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

8 **TITLE II—PHARMACY BENEFIT**
9 **MANAGER TRANSPARENCY**
10 **AND REBATE REFORM**

11 **SEC. 201. FULL REBATE ON INSULIN PASS-THROUGH TO**
12 **PLAN.**

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

17 **“SEC. 2799A–13. FULL REBATE ON INSULIN PASS-THROUGH**
18 **TO PLAN.**

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

1 from a pharmaceutical manufacturer, distributor or any
2 other third party, that are related to utilization of insulin
3 under such health plan or health insurance coverage, to
4 the group health plan.

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

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

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

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

18 (b) ERISA.—

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

1 **“SEC. 728. FULL REBATE ON INSULIN PASS-THROUGH TO**
2 **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 (2) CLERICAL AMENDMENT.—The table of con-
2 tents in section 1 of the Employee Retirement In-
3 come Security Act of 1974 (29 U.S.C. 1001 et seq.),
4 as amended by section 101, is further amended by
5 inserting after the item relating to section 727 the
6 following:

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

7 (c) INTERNAL REVENUE CODE.—

8 (1) IN GENERAL.—Subchapter B of chapter
9 100 of the Internal Revenue Code of 1986, as
10 amended by section 101, is further amended by add-
11 ing at the end the following new section:

12 **“SEC. 9828. FULL REBATE ON INSULIN PASS-THROUGH TO**
13 **PLAN.**

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

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

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

6 “(2) fully disclosed and enumerated to the
7 group health plan sponsor; and

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

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

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

15 **TITLE III—BIOSIMILAR BIOLOGI-**
16 **CAL PRODUCT AND GENERIC**
17 **DRUG COMPETITION AND AF-**
18 **FORDABILITY**

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

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

22 (1) in paragraph (1)—

23 (A) in subparagraph (A)(i), by inserting “,
24 10.31,” after “10.30”;

25 (B) in subparagraph (E)—

1 (i) by striking “application and” and
2 inserting “application or”;

3 (ii) by striking “If the Secretary” and
4 inserting the following:

5 “(i) IN GENERAL.—If the Secretary”;

6 and

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

9 “(ii) PRIMARY PURPOSE OF DELAY-
10 ING.—

11 “(I) IN GENERAL.—In deter-
12 mining whether a petition was sub-
13 mitted with the primary purpose of
14 delaying an application, the Secretary
15 may consider the following factors:

16 “(aa) Whether the petition
17 was submitted in accordance with
18 paragraph (2)(B), based on when
19 the petitioner knew or reasonably
20 should have known the relevant
21 information relied upon to form
22 the basis of such petition.

23 “(bb) Whether the petitioner
24 has submitted multiple or serial
25 petitions or supplements to peti-

1 tions raising issues that reason-
2 ably could have been known to
3 the petitioner at the time of sub-
4 mission of the earlier petition or
5 petitions.

6 “(cc) Whether the petition
7 was submitted close in time to a
8 known, first date upon which an
9 application under subsection
10 (b)(2) or (j) of this section or
11 section 351(k) of the Public
12 Health Service Act could be ap-
13 proved.

14 “(dd) Whether the petition
15 was submitted without relevant
16 data or information in support of
17 the scientific positions forming
18 the basis of such petition.

19 “(ee) Whether the petition
20 raises the same or substantially
21 similar issues as a prior petition
22 to which the Secretary has re-
23 sponded substantively already, in-
24 cluding if the subsequent submis-

1 sion follows such response from
2 the Secretary closely in time.

3 “(ff) Whether the petition
4 requests changing the applicable
5 standards that other applicants
6 are required to meet, including
7 requesting testing, data, or label-
8 ing standards that are more on-
9 erous or rigorous than the stand-
10 ards the Secretary has deter-
11 mined to be applicable to the list-
12 ed drug, reference product, or pe-
13 titioner’s version of the same
14 drug.

15 “(gg) The petitioner’s record
16 of submitting petitions to the
17 Food and Drug Administration
18 that have been determined by the
19 Secretary to have been submitted
20 with the primary purpose of
21 delay.

22 “(hh) Other relevant and
23 appropriate factors, which the
24 Secretary shall describe in guid-
25 ance.

1 “(II) GUIDANCE.—The Secretary
2 may issue or update guidance, as ap-
3 propriate, to describe factors the Sec-
4 retary considers in accordance with
5 subclause (I).”;

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

7 “(iii) REFERRAL TO THE FEDERAL
8 TRADE COMMISSION.—The Secretary shall
9 establish procedures for referring to the
10 Federal Trade Commission any petition or
11 supplement to a petition that the Secretary
12 determines was submitted with the primary
13 purpose of delaying approval of an applica-
14 tion. Such procedures shall include notifi-
15 cation to the petitioner by the Secretary.”;

16 (D) by striking subparagraph (F);

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

20 (F) in subparagraph (H), as so redesign-
21 ated, by striking “submission of this petition”
22 and inserting “submission of this document”;

23 (2) in paragraph (2)—

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

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

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

18 “(B) TIMELY SUBMISSION OF CITIZEN PE-
19 TITION.—A petition and any supplement to a
20 petition shall be submitted within 60 days after
21 the person knew, or reasonably should have
22 known, the information that forms the basis of
23 the request made in the petition or supple-
24 ment.”;

1 (C) in subparagraph (C), as so redesignig-
2 nated—

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

5 (ii) in clause (i), by striking “during
6 the 150-day period referred to in para-
7 graph (1)(F),”; and

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

10 “(ii) on or after the date that is 151
11 days after the date of submission of the
12 petition, the Secretary approves or has ap-
13 proved the application that is the subject
14 of the petition without having made such a
15 final decision.”;

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

18 “(D) DISMISSAL OF CERTAIN CIVIL AC-
19 TIONS.—

20 “(i) PETITION.—If a person files a
21 civil action against the Secretary in which
22 a person seeks to set aside, delay, rescind,
23 withdraw, or prevent submission, review, or
24 approval of an application submitted under
25 subsection (b)(2) or (j) of this section or

1 section 351(k) of the Public Health Service
2 Act without complying with the require-
3 ments of subparagraph (A), the court shall
4 dismiss without prejudice the action for
5 failure to exhaust administrative remedies.

6 “(ii) TIMELINESS.—If a person files a
7 civil action against the Secretary in which
8 a person seeks to set aside, delay, rescind,
9 withdraw, or prevent submission, review, or
10 approval of an application submitted under
11 subsection (b)(2) or (j) of this section or
12 section 351(k) of the Public Health Service
13 Act without complying with the require-
14 ments of subparagraph (B), the court shall
15 dismiss with prejudice the action for fail-
16 ure to timely file a petition.

17 “(iii) FINAL RESPONSE.—If a civil ac-
18 tion is filed against the Secretary with re-
19 spect to any issue raised in a petition time-
20 ly filed under paragraph (1) in which the
21 petitioner requests that the Secretary take
22 any form of action that could, if taken, set
23 aside, delay, rescind, withdraw, or prevent
24 submission, review, or approval of an appli-
25 cation submitted under subsection (b)(2)

1 or (j) of this section or section 351(k) of
2 the Public Health Service Act before the
3 Secretary has taken final agency action on
4 the petition within the meaning of sub-
5 paragraph (C), the court shall dismiss
6 without prejudice the action for failure to
7 exhaust administrative remedies.”; and

8 (E) in clause (iii) of subparagraph (E), as
9 so redesignated, by striking “as defined under
10 subparagraph (2)(A)” and inserting “within the
11 meaning of subparagraph (C)”;

12 (3) in paragraph (4)—

13 (A) by striking “EXCEPTIONS” and all that
14 follows through “This subsection does” and in-
15 serting “EXCEPTIONS.—This subsection does”;

16 (B) by striking subparagraph (B); and

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

20 **SEC. 302. EXPEDITING COMPETITIVE BIOSIMILAR COM-**
21 **PETITION.**

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

1 “(10) EXPEDITING COMPETITIVE BIOSIMILAR
2 COMPETITION.—

3 “(A) IN GENERAL.—The Secretary may, at
4 the request of the sponsor of an application
5 under this subsection for a biosimilar biological
6 product that is designated as a competitive bio-
7 similar therapy pursuant to subsection (b), ex-
8 pedite the development and review of such ap-
9 plication under this subsection.

10 “(B) DESIGNATION PROCESS.—

11 “(i) REQUEST.—The sponsor of an
12 application under this subsection may re-
13 quest the Secretary to designate the drug
14 as a competitive biosimilar therapy. A re-
15 quest for such designation may be made
16 concurrently with, or at any time prior to,
17 the submission of a biosimilar biological
18 product license application under this sub-
19 section.

20 “(ii) CRITERIA.—A biological product
21 is eligible for designation as a competitive
22 biosimilar therapy under this paragraph if
23 the Secretary determines that there is in-
24 adequate biosimilar competition.

1 “(iii) DESIGNATION.—Not later than
2 60 calendar days after the receipt of a re-
3 quest under clause (i), the Secretary
4 may—

5 “(I) determine whether the bio-
6 similar biological product that is the
7 subject of the request meets the cri-
8 teria described in clause (ii); and

9 “(II) if the Secretary finds that
10 such product meets such criteria, des-
11 ignate the biosimilar biological prod-
12 uct as a competitive biosimilar ther-
13 apy.

14 “(C) ACTIONS.—In expediting the develop-
15 ment and review of an application under sub-
16 paragraph (A), the Secretary may, as requested
17 by the applicant, take actions including the fol-
18 lowing:

19 “(i) Hold meetings with the sponsor
20 and the review team throughout the devel-
21 opment of the biosimilar biological product
22 prior to submission of the application
23 under this subsection.

24 “(ii) Provide timely advice to, and
25 interactive communication with, the spon-

1 sor regarding the development of the drug
2 to ensure that the development program to
3 gather the data necessary for approval is
4 as efficient as practicable.

5 “(iii) Involve senior managers and ex-
6 perience review staff, as appropriate, in a
7 collaborative, coordinated review of such
8 application, including with respect to bio-
9 logical product-device combination prod-
10 ucts and other complex products.

11 “(iv) Assign a cross-disciplinary
12 project lead—

13 “(I) to facilitate an efficient re-
14 view of the development program and
15 application, including manufacturing
16 inspections; and

17 “(II) to serve as a scientific liai-
18 son between the review team and the
19 applicant.

20 “(D) INSPECTIONS.—With respect to an
21 application described in subparagraph (A), in
22 the case of an inspection report that finds ap-
23 proval of such biological product is dependent
24 upon remediation of a facility, if the applicant
25 attests that necessary changes have been made

1 to the facility, the Secretary shall expedite rein-
2 spection of such facility, including establishing
3 a set timeline to reinspect the facility or make
4 a determination about the response of the appli-
5 cant and whether to approve the application.

6 “(E) REPORTING REQUIREMENT.—Not
7 later than 1 year after the date of licensure
8 under this subsection with respect to a bio-
9 similar biological product for which the develop-
10 ment and review is expedited under this para-
11 graph, the holder of the license of such bio-
12 similar biological product shall report to the
13 Secretary on whether the biosimilar biological
14 product has been marketed in interstate com-
15 merce since the date of such licensure.

16 “(F) INADEQUATE BIOSIMILAR COMPETI-
17 TION.—In this paragraph, the term ‘inadequate
18 biosimilar competition’ means, with respect to a
19 biological product, there are fewer than 3 li-
20 censed biological products on the list published
21 under paragraph (9)(A) (not including biologi-
22 cal products on the discontinued section of such
23 list) that are biosimilar biological products with
24 the same reference product.”.

1 **SEC. 303. INSULIN COMPETITION REPORT.**

2 Not later than 1 year after the date of the enactment
3 of this Act, the Secretary of Health and Human Services,
4 in collaboration with the Administrator for the Centers for
5 Medicare & Medicaid Services and the Commissioner of
6 Food and Drugs, shall—

7 (1) complete a study to determine the extent of,
8 and causes of, delays in getting insulin products to
9 market, and the market dynamics and extent bio-
10 similar biological product development and competi-
11 tion could increase, or is increasing, the number of
12 biological products approved and available to pa-
13 tients, including by examining barriers to—

14 (A) placement of biosimilar biological prod-
15 ucts on health insurance formularies;

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

19 (C) patient and provider education around
20 biosimilar biological products; and

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

1 **TITLE IV—PROGRAMS FOR PRO-**
2 **VIDING AFFORDABLE INSU-**
3 **LIN TO UNINSURED INDIVID-**
4 **UALS**

5 **SEC. 401. PILOT PROGRAM FOR PROVIDING AFFORDABLE**
6 **INSULIN TO UNINSURED INDIVIDUALS.**

7 Part P of title III of the Public Health Service Act
8 (42 U.S.C. 280g et seq.) is amended by adding at the end
9 the following:

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

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

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

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

21 “(2) have high rates of uninsured individuals
22 and individuals diagnosed with diabetes, which may
23 include high rates of newly diagnosed diabetes.

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

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

8 “(2) To enroll individuals in programs under
9 which drug manufacturers provide financial or medi-
10 cation assistance to low-income individuals, in order
11 to assist such individuals in obtaining insulin.

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

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

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

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

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

6 “(e) ACCOUNTABILITY AND OVERSIGHT.—A State
7 receiving a grant under this section shall, not later than
8 1 year after receiving the grant, submit a report to the
9 Secretary that includes—

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

14 “(2) the number of individuals served through
15 the grant.

16 “(f) DEFINITIONS.—In this section:

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

21 “(2) FEDERALLY-QUALIFIED HEALTH CEN-
22 TER.—The term ‘Federally-qualified health center’
23 has the meaning given such term in section
24 1905(l)(2) of the Social Security Act.

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

5 “(4) RETAIL COMMUNITY PHARMACY.—The
6 term ‘retail community pharmacy’ has the meaning
7 given such term in section 1927(k)(10) of the Social
8 Security Act.

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

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

15 “(B) 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), the
18 health program established under chapter 89 of
19 title 5, United States Code, or a group health
20 plan or group health insurance coverage (as de-
21 fined in section 2791); and

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

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

5 **SEC. 402. GAO STUDY ON UNINSURED INDIVIDUALS WHO**
6 **USE INSULIN.**

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

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

17 (2) any identifiable potential reasons for unin-
18 sured status;

19 (3) demographic characteristics of such individ-
20 uals, such as race and ethnicity; and

21 (4) income level of such individuals.

22 (b) DEFINITIONS.—In this section, the terms “insu-
23 lin” and “uninsured individual” have the meanings given
24 such terms in section 399V–8 of the Public Health Service
25 Act, as added by section 401.

1 **SEC. 403. INSULIN RESOURCE CENTER AND HOTLINE FOR**
2 **UNINSURED INDIVIDUALS.**

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

7 (1) establishing and maintaining a resource
8 center of assistance programs offered by manufac-
9 tures or other entities that are available to unin-
10 sured individuals seeking affordable insulin; and

11 (2) conducting the public education activities
12 described in subsection (e)(7).

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

15 (1) be a trade, industry, or professional associa-
16 tion, community- and consumer-focused nonprofit
17 entity, or other entity, as determined by the Sec-
18 retary that—

19 (A) is capable of carrying out the duties
20 described in subsection (e);

21 (B) meets the standards described in sub-
22 section (e); and

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

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

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

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

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

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

23 (2) facilitate enrollment in manufacturer assist-
24 ance programs or other assistance programs for un-
25 insured individuals;

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

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

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

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

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

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

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

16 (B) provides voice and text support; and

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

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

21 (7) conduct public education activities, in col-
22 laboration with the Department of Health and
23 Human Services, to raise awareness of the avail-
24 ability of all manufacturer, foundational, and other
25 assistance programs available to patients seeking af-

1 fordable insulin, with a focus on uninsured individ-
2 uals; including by—

3 (A) partnering with community health cen-
4 ters, hospitals, retail community pharmacies,
5 and community-based organizations with a
6 focus on access to affordable medicine; and

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

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

12 (1) ensure adequate maintenance of the re-
13 source center established by the entity receiving a
14 grant under subsection (a);

15 (2) publicize such resource center on the
16 website of the Department of Health and Human
17 Services and across Federal agencies, as the Sec-
18 retary determines appropriate; and

19 (3) ensure that such resource center meets the
20 standards under subsection (e), and withdraw the
21 grant and make an award to a different eligible enti-
22 ty in the case that an eligible entity fails to meet
23 such standards.

24 (e) STANDARDS.—The Secretary shall establish
25 standards for the resource center under this section, in-

1 cluding provisions to ensure that the entity receiving a
2 grant under this section is qualified to engage in the ac-
3 tivities described in this section and to avoid conflicts of
4 interest. Under such standards, such entity—

5 (1) shall not—

6 (A) be a manufacturer of insulin products;

7 or

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

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

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

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

21 (2) increases awareness of assistance programs
22 or foundational support available for uninsured indi-
23 viduals; and

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

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

12 (h) DEFINITIONS.—In this section—

13 (1) the term “assistance program” means a
14 program to assist patients in obtaining a drug at a
15 reduced cost, and includes third-party payments, fi-
16 nancial assistance, discounts, product vouchers, and
17 other reductions in out-of-pocket expenses;

18 (2) the term “Federally-qualified health center”
19 has the meaning given such term in section
20 1905(l)(2) of the Social Security Act (42 U.S.C.
21 1396d(1)(2));

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

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

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

7 (A) does not qualify for coverage under a
8 Federal health care program (as defined in sec-
9 tion 1128B(f) of the Social Security Act (42
10 U.S.C. 1320a-7b(f))), the health program es-
11 tablished under chapter 89 of title 5, United
12 States Code, or a group health plan or group
13 health insurance coverage (as defined in section
14 2791 of the Public Health Service Act (42
15 U.S.C. 300gg-91)); and

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

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