

118TH CONGRESS
1ST SESSION

S. 1269

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

APRIL 25, 2023

Mrs. SHAHEEN (for herself and Ms. COLLINS) introduced the following bill; which was read twice and referred to the Committee on Health, Education, Labor, and Pensions

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 2023” or the “INSULIN Act of
7 2023”.

8 (b) TABLE OF CONTENTS.—The table of contents for
9 this Act is as follows:

Sec. 1. Short title; table of contents.

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. Permitted mid-year changes in Medicare part D plan formularies for certain biosimilar biological products and the reference product of such biosimilars.

Sec. 303. Expediting competitive biosimilar competition.

Sec. 304. Insulin competition report.

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 lic Health Service Act (42 U.S.C. 300gg–111 et seq.) is
 7 amended by adding at the end the following:

8 **“SEC. 2799A–11. 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, 2024, 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

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

3 “(A) for any applicable plan year begin-
4 ning before January 1, 2025, \$35; or

5 “(B) for any plan year beginning on or
6 after January 1, 2025, the lesser of—

7 “(i) \$35; or

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

17 “(b) DEFINITIONS.—In this section:

18 “(1) SELECTED INSULIN PRODUCTS.—The term
19 ‘selected insulin products’ means, for any plan year
20 beginning on or after January 1, 2024, at least one
21 of each dosage form (such as vial, pen, or inhaler
22 dosage forms) of each different type (such as rapid-
23 acting, short-acting, intermediate-acting, long-acting,
24 and pre-mixed) of insulin, when such form is li-

1 censed and marketed, as selected by the group
2 health plan or health insurance issuer.

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

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

16 “(d) RULE OF CONSTRUCTION.—Subsection (a) shall
17 not be construed to require coverage of, or prevent a group
18 health plan or health insurance coverage from imposing
19 cost-sharing other than the levels specified in subsection
20 (a) on, insulin products that are not selected insulin prod-
21 ucts, to the extent that such coverage is not otherwise re-
22 quired and such cost-sharing is otherwise permitted under
23 Federal and applicable State law.

24 “(e) APPLICATION OF COST-SHARING TOWARDS
25 DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any

1 cost-sharing payments made pursuant to subsection (a)(2)
2 shall be counted toward any deductible or out-of-pocket
3 maximum that applies under the plan or coverage.

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

13 (b) NO EFFECT ON OTHER COST-SHARING.—Section
14 1302(d)(2) of the Patient Protection and Affordable Care
15 Act (42 U.S.C. 18022(d)(2)) is amended by adding at the
16 end the following new subparagraph:

17 “(D) SPECIAL RULE RELATING TO INSU-
18 LIN COVERAGE.—For plans years beginning on
19 or after January 1, 2025, the exemption of cov-
20 erage of selected insulin products (as defined in
21 section 2799A–11(b) of the Public Health Serv-
22 ice Act) from the application of any deductible
23 pursuant to section 2799A–11(a)(1) of such
24 Act, section 726(a)(1) of the Employee Retire-
25 ment Income Security Act of 1974, or section

1 9826(a)(1) of the Internal Revenue Code of
 2 1986 shall not be considered when determining
 3 the actuarial value of a qualified health plan
 4 under this subsection.”.

5 (c) COVERAGE OF CERTAIN INSULIN PRODUCTS
 6 UNDER CATASTROPHIC PLANS.—Section 1302(e) of the
 7 Patient Protection and Affordable Care Act (42 U.S.C.
 8 18022(e)) is amended by adding at the end the following:

9 “(4) COVERAGE OF CERTAIN INSULIN PROD-
 10 UCTS.—

11 “(A) IN GENERAL.—Notwithstanding para-
 12 graph (1)(B)(i), a health plan described in
 13 paragraph (1) shall provide coverage of selected
 14 insulin products, in accordance with section
 15 2799A–11 of the Public Health Service Act, be-
 16 fore an enrolled individual has incurred, during
 17 the plan year, cost-sharing expenses in an
 18 amount equal to the annual limitation in effect
 19 under subsection (c)(1) for the plan year.

20 “(B) TERMINOLOGY.—For purposes of
 21 subparagraph (A)—

22 “(i) the term ‘selected insulin prod-
 23 ucts’ has the meaning given such term in
 24 section 2799A–11(b) of the Public Health
 25 Service Act; and

1 “(ii) the requirements of section
 2 2799A–11 of such Act shall be applied by
 3 deeming each reference in such section to
 4 ‘individual health insurance coverage’ to be
 5 a reference to a plan described in para-
 6 graph (1).”.

7 (d) ERISA.—

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

12 **“SEC. 726. REQUIREMENTS WITH RESPECT TO COST-SHAR-**
 13 **ING FOR CERTAIN INSULIN PRODUCTS.**

14 “(a) IN GENERAL.—For plan years beginning on or
 15 after January 1, 2024, a group health plan or health in-
 16 surance issuer offering group health insurance coverage
 17 shall provide coverage of selected insulin products, and
 18 with respect to such products, shall not—

19 “(1) apply any deductible; or

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

22 “(A) for any applicable plan year begin-
 23 ning before January 1, 2025, \$35; or

24 “(B) for any plan year beginning on or
 25 after January 1, 2025, the lesser of—

1 “(i) \$35; or

2 “(ii) the amount equal to 25 percent
3 of the negotiated price of the selected insu-
4 lin product net of all price concessions re-
5 ceived by or on behalf of the plan or issuer,
6 including price concessions received by or
7 on behalf of third-party entities providing
8 services to the plan or issuer, such as
9 pharmacy benefit management services or
10 third party administrators.

11 “(b) DEFINITIONS.—In this section:

12 “(1) SELECTED INSULIN PRODUCTS.—The term
13 ‘selected insulin products’ means, for any plan year
14 beginning on or after January 1, 2024, at least one
15 of each dosage form (such as vial, pen, or inhaler
16 dosage forms) of each different type (such as rapid-
17 acting, short-acting, intermediate-acting, long-acting,
18 and pre-mixed) of insulin, when such form is li-
19 censed and marketed, as selected by the group
20 health plan or health insurance issuer.

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

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

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

23 “(f) OTHER REQUIREMENTS.—A group health plan
24 or health insurance issuer offering group health insurance
25 coverage shall not impose, directly or through an entity

1 providing pharmacy benefit management services, any
 2 prior authorization or other medical management require-
 3 ment, or other similar conditions, on selected insulin prod-
 4 ucts, except as clinically justified for safety reasons, to en-
 5 sure reasonable quantity limits and as specified by the
 6 Secretary.”.

7 (2) CLERICAL AMENDMENT.—The table of con-
 8 tents in section 1 of the Employee Retirement In-
 9 come Security Act of 1974 (29 U.S.C. 1001 et seq.)
 10 is amended by inserting after the item relating to
 11 section 725 the following:

“Sec. 726. Requirements with respect to cost-sharing for certain insulin prod-
 ucts.”.

12 (e) INTERNAL REVENUE CODE.—

13 (1) IN GENERAL.—Subchapter B of chapter
 14 100 of the Internal Revenue Code of 1986 is amend-
 15 ed by adding at the end the following new section:

16 **“SEC. 9826. REQUIREMENTS WITH RESPECT TO COST-SHAR-**
 17 **ING FOR CERTAIN INSULIN PRODUCTS.**

18 “(a) IN GENERAL.—For plan years beginning on or
 19 after January 1, 2024, a group health plan shall provide
 20 coverage of selected insulin products, and with respect to
 21 such products, shall not—

22 “(1) apply any deductible; or

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

1 “(A) for any applicable plan year begin-
2 ning before January 1, 2025, \$35; or

3 “(B) for any plan year beginning on or
4 after January 1, 2025, the lesser of—

5 “(i) \$35; or

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

15 “(b) DEFINITIONS.—In this section:

16 “(1) SELECTED INSULIN PRODUCTS.—The term
17 ‘selected insulin products’ means, for any plan year
18 beginning on or after January 1, 2024, at least one
19 of each dosage form (such as vial, pen, or inhaler
20 dosage forms) of each different type (such as rapid-
21 acting, short-acting, intermediate-acting, long-acting,
22 and pre-mixed) of insulin, when such form is li-
23 censed and marketed, as selected by the group
24 health plan.

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

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

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

23 “(e) APPLICATION OF COST-SHARING TOWARDS
24 DEDUCTIBLES AND OUT-OF-POCKET MAXIMUMS.—Any
25 cost-sharing payments made pursuant to subsection (a)(2)

1 shall be counted toward any deductible or out-of-pocket
2 maximum that applies under the plan.

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

10 (2) CLERICAL AMENDMENT.—The table of sec-
11 tions for subchapter B of chapter 100 of such Code,
12 as amended by section 102(c)(2), is further amended
13 by adding at the end the following new item:

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

14 **SEC. 102. APPLICATION TO RETIREE AND CERTAIN SMALL**
15 **GROUP PLANS.**

16 (a) ERISA.—Section 732(a) of the Employee Retire-
17 ment Income Security Act of 1974 (29 U.S.C. 1191a(a))
18 is amended by striking “section 711” and inserting “sec-
19 tions 711 and 726”.

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

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

1 “Paragraph (2) shall not apply to the requirements under
2 sections 9811 and 9826.”; and

3 (2) in section 4980D(d)(1), by striking “section
4 9811” and inserting “sections 9811 and 9826”.

5 **SEC. 103. ADMINISTRATION.**

6 (a) IMPLEMENTATION.—Notwithstanding any other
7 provision of law, the Secretary of Health and Human
8 Services, the Secretary of Labor, and the Secretary of the
9 Treasury may implement the provisions of, including the
10 amendments made by, this title for plan years that begin
11 on or after January 1, 2024, and end not later than Janu-
12 ary 1, 2027, by subregulatory guidance, program instruc-
13 tion, or otherwise.

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

1 **TITLE II—PHARMACY BENEFIT**
 2 **MANAGER TRANSPARENCY**
 3 **AND REBATE REFORM**

4 **SEC. 201. FULL REBATE ON INSULIN PASS-THROUGH TO**
 5 **PLAN.**

6 Part A of title XXVII of the Public Health Service
 7 Act (42 U.S.C. 300gg et seq.) is further amended by add-
 8 ing at the end the following:

9 **“SEC. 2729A. FULL REBATE ON INSULIN PASS-THROUGH TO**
 10 **PLAN.**

11 “(a) IN GENERAL.—A pharmacy benefits manager,
 12 a third-party administrator of a group health plan, a
 13 health insurance issuer offering group health insurance
 14 coverage, or an entity providing pharmacy benefits man-
 15 agement services under such health plan or health insur-
 16 ance coverage shall remit 100 percent of rebates, fees, al-
 17 ternative discounts, and all other remuneration received
 18 from a pharmaceutical manufacturer, distributor or any
 19 other third party, that are related to utilization of insulin
 20 under such health plan or health insurance coverage, to
 21 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 **TITLE III—BIOSIMILAR BIOLOGI-**
12 **CAL PRODUCT AND GENERIC**
13 **DRUG COMPETITION AND AF-**
14 **FORDABILITY**

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

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

18 (1) in paragraph (1)—

19 (A) in subparagraph (A)(i), by inserting “,
20 10.31,” after “10.30”;

21 (B) in subparagraph (E)—

22 (i) by striking “application and” and
23 inserting “application or”;

24 (ii) by striking “If the Secretary” and
25 inserting the following:

1 “(i) IN GENERAL.—If the Secretary”;

2 and

3 (iii) by striking the second sentence

4 and inserting the following:

5 “(ii) PRIMARY PURPOSE OF DELAY-
6 ING.—

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

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

19 “(bb) Whether the petitioner
20 has submitted multiple or serial
21 petitions or supplements to peti-
22 tions raising issues that reason-
23 ably could have been known to
24 the petitioner at the time of sub-

1 mission of the earlier petition or
2 petitions.

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

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

16 “(ee) Whether the petition
17 raises the same or substantially
18 similar issues as a prior petition
19 to which the Secretary has re-
20 sponded substantively already, in-
21 cluding if the subsequent submis-
22 sion follows such response from
23 the Secretary closely in time.

24 “(ff) Whether the petition
25 requests changing the applicable

1 standards that other applicants
2 are required to meet, including
3 requesting testing, data, or label-
4 ing standards that are more on-
5 erous or rigorous than the stand-
6 ards the Secretary has deter-
7 mined to be applicable to the list-
8 ed drug, reference product, or pe-
9 titioner's version of the same
10 drug.

11 “(gg) The petitioner's record
12 of submitting petitions to the
13 Food and Drug Administration
14 that have been determined by the
15 Secretary to have been submitted
16 with the primary purpose of
17 delay.

18 “(hh) Other relevant and
19 appropriate factors, which the
20 Secretary shall describe in guid-
21 ance.

22 “(II) GUIDANCE.—The Secretary
23 may issue or update guidance, as ap-
24 propriate, to describe factors the Sec-

1 retary considers in accordance with
2 subclause (I).”;

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

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

13 (D) by striking subparagraph (F);

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

17 (F) in subparagraph (H), 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
2 a 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)
7 or (j) of this section or section 351(k) of the
8 Public Health Service Act. Such petition and
9 any supplement to such a petition shall describe
10 all information and arguments that form the
11 basis of the relief requested in any civil action
12 described in the previous sentence.

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

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

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

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

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

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

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

14 “(D) DISMISSAL OF CERTAIN CIVIL AC-
15 TIONS.—

16 “(i) PETITION.—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 (A), the court shall

1 dismiss without prejudice the action for
2 failure to exhaust administrative remedies.

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

14 “(iii) FINAL RESPONSE.—If a civil ac-
15 tion is filed against the Secretary with re-
16 spect to any issue raised in a petition time-
17 ly filed under paragraph (1) in which the
18 petitioner requests that the Secretary take
19 any form of action that could, if taken, set
20 aside, delay, rescind, withdraw, or prevent
21 submission, review, or approval of an appli-
22 cation submitted under subsection (b)(2)
23 or (j) of this section or section 351(k) of
24 the Public Health Service Act before the
25 Secretary has taken final agency action on

1 the petition within the meaning of sub-
 2 paragraph (C), the court shall dismiss
 3 without prejudice the action for failure to
 4 exhaust administrative remedies.”; and

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

9 (3) in paragraph (4)—

10 (A) by striking “EXCEPTIONS” and all that
 11 follows through “This subsection does” and in-
 12 serting “EXCEPTIONS.—This subsection does”;

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

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

17 **SEC. 302. PERMITTED MID-YEAR CHANGES IN MEDICARE**
 18 **PART D PLAN FORMULARIES FOR CERTAIN**
 19 **BIOSIMILAR BIOLOGICAL PRODUCTS AND**
 20 **THE REFERENCE PRODUCT OF SUCH**
 21 **BIOSIMILARS.**

22 (a) IN GENERAL.—Section 1860D–4(b) of the Social
 23 Security Act (42 5 U.S.C. 1395w–104(b)) is amended by
 24 adding at the end the following new paragraph:

1 “(5) MID-YEAR CHANGES IN FORMULARIES
2 PERMITTED FOR CERTAIN BIOSIMILAR BIOLOGICAL
3 PRODUCTS AND THE REFERENCE PRODUCT OF SUCH
4 BIOSIMILARS.—If a PDP sponsor of a prescription
5 drug plan uses a formulary (including the use of
6 tiered cost-sharing), the following shall apply:

7 “(A) IN GENERAL.—For plan year 2024,
8 and subsequent plan years, in the case of a cov-
9 ered part D drug that is the reference biological
10 product (as defined in section 1847A(c)(6)(I))
11 with respect to a biosimilar biological product
12 (as defined in section 1847A(c)(6)(H)), the
13 PDP sponsor may, with respect to a formulary,
14 at any time after the first 60 days of the plan
15 year, subject to paragraph (3)(E), change the
16 preferred or tiered cost-sharing status of such
17 reference biological product if such PDP spon-
18 sor adds, at the same time, to such formulary
19 such biosimilar biological product at the same
20 or a higher preferred status, or to the same or
21 lower cost-sharing tier, as that of such ref-
22 erence biological product immediately prior to
23 such change.

24 “(B) REQUEST FOR APPROVAL OF
25 CHANGE.—Prior to making a change described

1 in clause (i), the PDP sponsor shall submit to
2 the Secretary a request to make such change.
3 If the Secretary approves the request or has not
4 provided a decision to the PDP sponsor regard-
5 ing such request within 30 days of receiving
6 such request, such PDP sponsor may make
7 such change.”.

8 (b) ADMINISTRATION.—

9 (1) IMPLEMENTATION.—Notwithstanding any
10 other provision of law, the Secretary of Health and
11 Human Services may implement the amendment
12 made by subsection (a) by subregulatory guidance,
13 program instruction, or otherwise.

14 (2) NON-APPLICATION OF THE PAPERWORK RE-
15 DUCION ACT.—Chapter 35 of title 44, United
16 States Code (commonly referred to as the “Paper-
17 work Reduction Act of 1995”), shall not apply to the
18 implementation of the amendment made by sub-
19 section (a).

20 **SEC. 303. 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 periented 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. 304. 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.

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