118TH CONGRESS
1ST 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 and Ms. COLLINS) 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.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Improving Needed Safeguards for Users of Lifesaving Insulin Now Act of 2023'' or the ''INSULIN Act of 2023''.

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

TITLE I—COMMERCIAL MARKET PATIENT PROTECTIONS

SEC. 101. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

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

"SEC. 2799A–11. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

''(a) IN GENERAL.—For plan years beginning on or after January 1, 2024, a group health plan or health insurance issuer offering group or individual health insurance coverage shall provide coverage of selected insulin products, and with respect to such products, shall not—

''(1) apply any deductible; or

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

"(A) for any applicable plan year beginning before January 1, 2025, $35; or

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

"(i) $35; or

"(ii) the amount equal to 25 percent of the negotiated price of the selected insulin product net of all price concessions received by or on behalf of the plan or issuer, including price concessions received by or on behalf of third-party entities providing services to the plan or issuer, such as pharmacy benefit management services or third party administrators.

"(b) DEFINITIONS.—In this section:

"(1) SELECTED INSULIN PRODUCTS.—The term 'selected insulin products' means, for any plan year beginning on or after January 1, 2024, 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 insulin that is licensed under subsection (a) or (k) of section 351 and continues to be marketed pursuant to such licensure.

''(c) OUT-OF-NETWORK PROVIDERS.—Nothing in this section requires a plan or issuer that has a network of providers to provide benefits for selected insulin products described in this section that are delivered by an out-of-network provider, or precludes a plan or issuer that has a network of providers from imposing higher cost-sharing than the levels specified in subsection (a) for selected insulin products described in this section that are delivered by an out-of-network provider.

''(d) RULE OF CONSTRUCTION.—Subsection (a) shall not be construed to require coverage of, or prevent a group health plan or health insurance coverage from imposing cost-sharing other than the levels specified in subsection (a) on, insulin products that are not selected insulin products, to the extent that such coverage is not otherwise required and such cost-sharing is otherwise permitted under Federal and applicable State law.

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

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

''(f) OTHER REQUIREMENTS.—A group health plan or health insurance issuer offering group or individual health insurance coverage shall not impose, directly or through an entity providing pharmacy benefit management services, any prior authorization or other medical management requirement, or other similar conditions, on selected insulin products, except as clinically justified for safety reasons, to ensure reasonable quantity limits and as specified by the Secretary.''.

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

''(D) SPECIAL RULE RELATING TO INSULIN COVERAGE.—For plans years beginning on or after January 1, 2025, the exemption of coverage of selected insulin products (as defined in section 2799A–11(b) of the Public Health Service Act) from the application of any deductible pursuant to section 2799A–11(a)(1) of such Act, section 726(a)(1) of the Employee Retirement Income Security Act of 1974, or section

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

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

''(4) COVERAGE OF CERTAIN INSULIN PRODUCTS.—

''(A) IN GENERAL.—Notwithstanding paragraph (1)(B)(i), a health plan described in paragraph (1) shall provide coverage of selected insulin products, in accordance with section 2799A–11 of the Public Health Service Act, before an enrolled individual has incurred, during the plan year, cost-sharing expenses in an amount equal to the annual limitation in effect under subsection (c)(1) for the plan year.

''(B) TERMINOLOGY.—For purposes of subparagraph (A)—

''(i) the term 'selected insulin products' has the meaning given such term in section 2799A–11(b) of the Public Health Service Act; and

''(ii) the requirements of section 2799A–11 of such Act shall be applied by deeming each reference in such section to 'individual health insurance coverage' to be a reference to a plan described in paragraph (1).''.

(d) ERISA.—

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

''SEC. 726. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

''(a) IN GENERAL.—For plan years beginning on or after January 1, 2024, a group health plan or health insurance issuer offering group health insurance coverage shall provide coverage of selected insulin products, and with respect to such products, shall not—

''(1) apply any deductible; or

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

''(A) for any applicable plan year beginning before January 1, 2025, $35; or

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

''(i) $35; or

''(ii) the amount equal to 25 percent of the negotiated price of the selected insulin product net of all price concessions received by or on behalf of the plan or issuer, including price concessions received by or on behalf of third-party entities providing services to the plan or issuer, such as pharmacy benefit management services or third party administrators.

''(b) DEFINITIONS.—In this section:

''(1) SELECTED INSULIN PRODUCTS.—The term 'selected insulin products' means, for any plan year beginning on or after January 1, 2024, at least one of each dosage form (such as vial, pen, or inhaler dosage forms) of each different type (such as rapid-acting, short-acting, intermediate-acting, long-acting, and pre-mixed) of insulin, when such form is licensed and marketed, as selected by the group health plan or health insurance issuer.

''(2) INSULIN.—The term 'insulin' means insulin that is licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) and continues to be marketed pursuant to such licensure.

''(c) OUT-OF-NETWORK PROVIDERS.—Nothing in this section requires a plan or issuer that has a network of providers to provide benefits for selected insulin products described in this section that are delivered by an out-of-network provider, or precludes a plan or issuer that has a network of providers from imposing higher cost-sharing than the levels specified in subsection (a) for selected insulin products described in this section that are delivered by an out-of-network provider.

''(d) RULE OF CONSTRUCTION.—Subsection (a) shall not be construed to require coverage of, or prevent a group health plan or health insurance coverage from imposing cost-sharing other than the levels specified in subsection (a) on, insulin products that are not selected insulin products, to the extent that such coverage is not otherwise required and such cost-sharing is otherwise permitted under Federal and applicable State law.

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

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

providing pharmacy benefit management services, any prior authorization or other medical management requirement, or other similar conditions, on selected insulin products, except as clinically justified for safety reasons, to ensure reasonable quantity limits and as specified by the Secretary.''.

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001 et seq.) is amended by inserting after the item relating to section 725 the following:

''Sec. 726. Requirements with respect to cost-sharing for certain insulin products.''.

(e) INTERNAL REVENUE CODE.—

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

''SEC. 9826. REQUIREMENTS WITH RESPECT TO COST-SHARING FOR CERTAIN INSULIN PRODUCTS.

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

''(1) apply any deductible; or

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

"(A) for any applicable plan year beginning before January 1, 2025, $35; or

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

"(i) $35; or

"(ii) the amount equal to 25 percent of the negotiated price of the selected insulin product net of all price concessions received by or on behalf of the plan, including price concessions received by or on behalf of third-party entities providing services to the plan, such as pharmacy benefit management services or third party administrators.

"(b) DEFINITIONS.—In this section:

"(1) SELECTED INSULIN PRODUCTS.—The term 'selected insulin products' means, for any plan year beginning on or after January 1, 2024, at least one of each dosage form (such as vial, pen, or inhaler dosage forms) of each different type (such as rapid-acting, short-acting, intermediate-acting, long-acting, and pre-mixed) of insulin, when such form is licensed and marketed, as selected by the group health plan.

''(2) INSULIN.—The term 'insulin' means insulin that is licensed under subsection (a) or (k) of section 351 of the Public Health Service Act (42 U.S.C. 262) and continues to be marketed pursuant to such licensure.

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

''(d) RULE OF CONSTRUCTION.—Subsection (a) shall not be construed to require coverage of, or prevent a group health plan from imposing cost-sharing other than the levels specified in subsection (a) on, insulin products that are not selected insulin products, to the extent that such coverage is not otherwise required and such cost-sharing is otherwise permitted under Federal and applicable State law.

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

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

''(f) OTHER REQUIREMENTS.—A group health plan shall not impose, directly or through an entity providing pharmacy benefit management services, any prior authorization or other medical management requirement, or other similar conditions, on selected insulin products, except as clinically justified for safety reasons, to ensure reasonable quantity limits and as specified by the Secretary''.

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

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

SEC. 102. APPLICATION TO RETIREE AND CERTAIN SMALL GROUP PLANS.

(a) ERISA.—Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191a(a)) is amended by striking ''section 711'' and inserting ''sections 711 and 726''.

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

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

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

(2) in section 4980D(d)(1), by striking ''section 9811'' and inserting ''sections 9811and 9826''.

SEC. 103. ADMINISTRATION.

(a) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary of Health and Human Services, the Secretary of Labor, and the Secretary of the Treasury may implement the provisions of, including the amendments made by, this title for plan years that begin on or after January 1, 2024, and end not later than January 1, 2027, by subregulatory guidance, program instruction, or otherwise.

(b) NON-APPLICATION OF THE PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code (commonly referred to as the ''Paperwork Reduction Act of 1995''), shall not apply to the provisions of, including the amendments made by, this title.

TITLE II—PHARMACY BENEFIT MANAGER TRANSPARENCY AND REBATE REFORM

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

Part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.), , is further amended by adding at the end the following:

"SEC. 2729A. FULL REBATE ON INSULIN PASS-THROUGH TO PLAN.

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

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

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

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

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

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

SEC. 301. ENSURING TIMELY ACCESS TO GENERICS.

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

(1) in paragraph (1)—

(A) in subparagraph (A)(i), by inserting '', 10.31,'' after ''10.30'';

(B) in subparagraph (E)—

(i) by striking ''application and'' and inserting ''application or'';

(ii) by striking ''If the Secretary'' and inserting the following:

''(i) IN GENERAL.—If the Secretary'';

and

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

''(ii) PRIMARY PURPOSE OF DELAYING.—

''(I) IN GENERAL.—In determining whether a petition was submitted with the primary purpose of delaying an application, the Secretary may consider the following factors:

''(aa) Whether the petition was submitted in accordance with paragraph (2)(B), based on when the petitioner knew or reasonably should have known the relevant information relied upon to form the basis of such petition.

''(bb) Whether the petitioner has submitted multiple or serial petitions or supplements to petitions raising issues that reasonably could have been known to the petitioner at the time of sub-

mission of the earlier petition or petitions.

''(cc) Whether the petition was submitted close in time to a known, first date upon which an application under subsection (b)(2) or (j) of this section or section 351(k) of the Public Health Service Act could be approved.

''(dd) Whether the petition was submitted without relevant data or information in support of the scientific positions forming the basis of such petition.

''(ee) Whether the petition raises the same or substantially similar issues as a prior petition to which the Secretary has responded substantively already, including if the subsequent submission follows such response from the Secretary closely in time.

''(ff) Whether the petition requests changing the applicable

standards that other applicants are required to meet, including requesting testing, data, or labeling standards that are more onerous or rigorous than the standards the Secretary has determined to be applicable to the listed drug, reference product, or petitioner's version of the same drug.

''(gg) The petitioner's record of submitting petitions to the Food and Drug Administration that have been determined by the Secretary to have been submitted with the primary purpose of delay.

''(hh) Other relevant and appropriate factors, which the Secretary shall describe in guidance.

''(II) GUIDANCE.—The Secretary may issue or update guidance, as appropriate, to describe factors the Sec-

retary considers in accordance with subclause (I).'';

(C) by adding at the end the following:

''(iii) REFERRAL TO THE FEDERAL TRADE COMMISSION.—The Secretary shall establish procedures for referring to the Federal Trade Commission any petition or supplement to a petition that the Secretary determines was submitted with the primary purpose of delaying approval of an application. 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 basis of the relief requested in any civil action described in the previous sentence.

"(B) TIMELY SUBMISSION OF CITIZEN PETITION.—A petition and any supplement to a petition shall be submitted within 60 days after the person knew, or reasonably should have known, the information that forms the basis of the request made in the petition or supplement.";

(C) in subparagraph (C), as so redesignated—

(i) in the heading, by striking "WITHIN 150 DAYS";

(ii) in clause (i), by striking ''during the 150-day period referred to in paragraph (1)(F),''; and

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

''(ii) on or after the date that is 151 days after the date of submission of the petition, the Secretary approves or has approved the application that is the subject of the petition without having made such a final decision.'';

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

''(D) DISMISSAL OF CERTAIN CIVIL ACTIONS.—

''(i) PETITION.—If a person files a civil action against the Secretary in which a 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 without complying with the requirements of subparagraph (A), the court shall

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

''(ii) TIMELINESS.—If a person files a civil action against the Secretary in which a 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 without complying with the requirements 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)''; and

(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. PERMITTED MID-YEAR CHANGES IN MEDICARE PART D PLAN FORMULARIES FOR CERTAIN BIOSIMILAR BIOLOGICAL PRODUCTS AND THE REFERENCE PRODUCT OF SUCH BIOSIMILARS.

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

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

"(A) IN GENERAL.—For plan year 2024, and subsequent plan years, in the case of a covered part D drug that is the reference biological product (as defined in section 1847A(c)(6)(I)) with respect to a biosimilar biological product (as defined in section 1847A(c)(6)(H)), the PDP sponsor may, with respect to a formulary, at any time after the first 60 days of the plan year, subject to paragraph (3)(E), change the preferred or tiered cost-sharing status of such reference biological product if such PDP sponsor adds, at the same time, to such formulary such biosimilar biological product at the same or a higher preferred status, or to the same or lower cost-sharing tier, as that of such reference biological product immediately prior to such change.

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

in clause (i), the PDP sponsor shall submit to the Secretary a request to make such change. If the Secretary approves the request or has not provided a decision to the PDP sponsor regarding such request within 30 days of receiving such request, such PDP sponsor may make such change.''.

(b) ADMINISTRATION.—

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

(2) NON-APPLICATION OF THE PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code (commonly referred to as the ''Paperwork Reduction Act of 1995''), shall not apply to the implementation of the amendment made by subsection (a).

SEC. 303. 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 as a competitive biosimilar therapy. A request for such designation may be made concurrently with, or at any time prior to, the submission of a biosimilar biological product license application under this subsection.

"(ii) CRITERIA.—A biological product is eligible for designation as a competitive biosimilar therapy 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

"(II) if the Secretary finds that such product meets such criteria, designate the biosimilar biological product as a competitive biosimilar therapy.

"(C) ACTIONS.—In expediting the development and review of an application under subparagraph (A), the Secretary may, as requested by the applicant, take actions including the following:

"(i) Hold meetings with the sponsor and the review team throughout the development of the biosimilar biological product prior to submission of the application under this subsection.

"(ii) Provide timely advice to, and interactive communication with, the spon-

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

''(iii) Involve senior managers and experienced review staff, as appropriate, in a collaborative, coordinated review of such application, including with respect to biological product-device combination products and other complex products.

''(iv) Assign a cross-disciplinary project lead—

''(I) to facilitate an efficient review of the development program and application, including manufacturing inspections; and

''(II) to serve as a scientific liaison between the review team and the applicant.

''(D) INSPECTIONS.—With respect to an application described in subparagraph (A), in the case of an inspection report that finds approval of such biological product is dependent upon remediation of a facility, if the applicant attests that necessary changes have been made

to the facility, the Secretary shall expedite reinspection of such facility, including establishing a set timeline to reinspect the facility or make a determination about the response of the applicant and whether to approve the application.

''(E) REPORTING REQUIREMENT.—Not later than 1 year after the date of licensure under this subsection with respect to a biosimilar biological product for which the development and review is expedited under this paragraph, the holder of the license of such biosimilar biological product shall report to the Secretary on whether the biosimilar biological product has been marketed in interstate commerce since the date of such licensure.

''(F) INADEQUATE BIOSIMILAR COMPETITION.—In this paragraph, the term 'inadequate biosimilar competition' means, with respect to a biological product, there are fewer than 3 licensed biological products on the list published under paragraph (9)(A) (not including biological products on the discontinued section of such list) that are biosimilar biological products with the same reference product.''.

SEC. 304. INSULIN COMPETITION REPORT.

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

(1) complete a study to determine the extent of, and causes of, delays in getting insulin products to market, and the market dynamics and extent biosimilar biological product development and competition could increase, or is increasing, the number of biological products approved and available to patients, including by examining barriers to—

(A) placement of biosimilar biological products on health insurance formularies;

(B) market entry of insulin product in the United States, as compared to other highly developed nations; and

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

(2) submit a report to Congress that describes the results of the study conducted pursuant to paragraph (1) and recommended policy solutions.