116TH CONGRESS
1ST SESSION

S. _____

To provide patient protections with respect to the cost of insulin.

IN THE SENATE OF THE UNITED STATES

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

A BILL

To provide 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.

This Act may be cited as the ''Insulin Price Reduction Act''.

SEC. 2. INSULIN PRICE PROTECTIONS.

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

"SEC. 2729A. INSULIN PRICE PROTECTIONS.

"(a) CONTRACTING REQUIREMENTS.—

"(1) IN GENERAL.—

"(A) REQUIREMENT.—Except as provided in subparagraph (B), a group health plan or a health insurance issuer offering group or individual health insurance coverage shall not, and shall ensure that any entity that provides pharmacy benefits management services under a contract with any such health plan or health insurance coverage does not, directly or indirectly, receive from a manufacturer of certified insulin a rebate, reduction in price, or other remuneration with respect to such insulin received by an enrollee in the plan or coverage and covered by the plan or coverage.

"(B) EXCEPTION.—The requirement under subparagraph (A) shall not apply to—

"(i) any such reduction in price that is reflected at the point of sale to the enrollee; or

"(ii) any remuneration that is a flat fee-based service fee that a manufacturer of such insulin pays to a pharmacy benefit manager for services rendered to the manufacturer that relate to arrangements by

the pharmacy benefit manager to provide pharmacy benefit management services to a health plan or health insurance issuer, if certain conditions established by the Secretary are met, including requirements that the fees are transparent to the health plan or health insurance issuer.

''(2) APPLICABILITY.—The restriction under paragraph (1) shall apply with respect to insulin described in paragraph (1), for which the manufacturer has certified the list price in accordance with section 5(b) of the Insulin Price Reduction Act with respect to—

''(A) any plan year in which the list price for insulin is certified under section 5(b)(2)(A) of the Insulin Price Reduction Act; and

''(B) each subsequent plan year during which the manufacturer limits any increase in the list price to the price that gave rise to the restriction under paragraph (1), adjusted by not more than the price change in the medical care component of the consumer price index for all urban consumers (U.S. city average), as certified under section 5(b)(2)(B) of the Insulin Price Reduction Act.

''(b) DEDUCTIBLE LIMITATION.—A group health plan or a health insurance issuer offering group or individual health insurance coverage shall not apply any deductible amount that otherwise is applicable to prescription drugs with respect to coverage of certified insulin under such plan or coverage, during the period described in subsection (a)(2).

''(c) HOLD HARMLESS.—In the first 2 plan years during which paragraph (1) applies with respect to an insulin certified under section 5(b) of the Insulin Price Reduction Act, a group health plan or a health insurance issuer offering group or individual health insurance coverage shall not, and shall ensure that any entity that provides pharmacy benefits management services under a contract with such health plan or health insurance coverage does not—

''(1) remove such insulin from the formulary applicable to the plan or coverage;

''(2) impose higher cost-sharing with respect to such insulin than the cost-sharing that applied with respect to the insulin in the year in which the list price reduction certification was provided under section 5(b)(2)(A) of the Insulin Price Reduction Act;

''(3) impose any prior authorization requirements for coverage of such insulin that were not ap-

plied during the year in which the list price reduction certification was provided under such section 5(b)(2)(A); or

''(4) establish a step therapy requirement for such insulin that was not applied during the year in which the list price reduction certification was provided under such section 5(b)(2)(A).

''(d) DEFINITIONS.—In this section—

''(1) the term 'certified insulin' means, with respect to a year, insulin that has been certified under section 5(b) of the Insulin Price Reduction Act for the year;

''(2) the term 'insulin' means any insulin product approved by the Food and Drug Administration to improve glycemic control in patients with diabetes mellitus;

''(3) the term 'list price' has the meaning given the term 'wholesale acquisition cost' in section 1847A(c)(6)(B) of the Social Security Act; and

''(4) the term 'rebate' means any discount, price concession, or fee, other than the fee described in section (a)(1)(B), the terms of which are fixed at the time of the sale and disclosed, but which is not received at the time of the sale.''.

(b) CONFORMING AMENDMENT.—Paragraph (2) of section 223(d) of the Internal Revenue Code of 1986 is amended by redesignating subparagraph (D) as subparagraph (E) and by inserting after subparagraph (C) the following new subparagraph:

"(D) SAFE HARBOR FOR ABSENCE OF DEDUCTIBLE FOR INSULIN.—A plan shall not fail to be treated as a high deductible health plan by reason of exempting insulin from any deductible pursuant to section 2729A(b) of the Public Health Service Act during the period described in section 2729A(a)(2) of such Act.".

(c) EFFECTIVE DATE.—The amendments made by subsections (a) and (b) shall take effect with respect to plan years beginning on or after January 1, 2022.

SEC. 3. INSULIN PRICE PROTECTIONS UNDER MEDICARE PART D.

Section 1860D–4 of the Social Security Act (42 U.S.C. 1395w–104) is amended—

(1) by redesignating the subsection (m) as added by section 6063(c) of the SUPPORT for Patients and Communities Act (Public Law 115–271) as subsection (n); and

(2) by adding at the end the following new subsection:

"(o) LIMITATION ON REBATES, PRICE REDUCTIONS, OR OTHER REMUNERATION FOR CERTIFIED INSULIN.—

"(1) LIMITATION.—

"(A) IN GENERAL.—Subject to subparagraphs (B) and (C), for plan year 2022 and subsequent plan years, a PDP sponsor and a Medicare Advantage organization shall ensure that each prescription drug plan or MA–PD plan offered by the sponsor or organization, and any entity that provides pharmacy benefits management services under a contract with the prescription drug plan or MA–PD plan offered by the sponsor or organization, does not, directly or indirectly, receive from a manufacturer of certified insulin a rebate, reduction in price, or other remuneration with respect to certified insulin that is covered by the plan.

"(B) EXCEPTION.—The requirement under subparagraph (A) shall not apply to—

"(i) any such reduction in price that is reflected at the point of sale to the beneficiary; or

"(ii) any remuneration that is a flat fee-based service fee that a manufacturer of such certified insulin pays to a phar-

macy benefit manager for services rendered to the manufacturer that relate to arrangements by the pharmacy benefit manager to provide pharmacy benefit management services to a prescription drug plan or MA–PD plan, if certain conditions established by the Secretary are met, including requirements that the fees are transparent to the prescription drug plan or MA–PD plan.

''(C) HOLD HARMLESS FOR FIRST 2 YEARS THAT AN INSULIN IS CERTIFIED.—In the first 2 plan years during which paragraph (2) applies with respect to a certified insulin, a PDP sponsor and a Medicare Advantage organization shall not, and shall ensure that any entity that provides pharmacy benefits management services under a contract with such sponsor or organization does not—

''(i) remove such insulin from the formulary applicable to the prescription drug plan or MA–PD plan;

''(ii) impose higher cost-sharing with respect to such insulin than the cost-sharing that applied with respect to the cer-

tified insulin in the year in which the list price reduction certification was provided under section 5(b)(2)(A) of the Insulin Price Reduction Act;

''(iii) impose any prior authorization requirements for coverage of the certified insulin that were not applied during the year in which the list price reduction certification was provided under such section 5(b)(2)(A); or

''(iv) establish a step therapy requirement for the certified insulin that was not applied during the year in which the list price reduction certification was provided under such section 5(b)(2)(A).

''(2) DEFINITIONS.—In this section:

''(A) CERTIFIED INSULIN.—The term 'certified insulin' means, with respect to a year, insulin that has been certified under section 5(b) of the Insulin Price Reduction Act for the year.

''(B) INSULIN.—The term 'insulin' means any insulin product approved by the Food and Drug Administration to improve glycemic control in patients with diabetes mellitus.

''(C) LIST PRICE.—The term 'list price' has the meaning given the term 'wholesale acquisition cost' in section 1847A(c)(6)(B).

''(D) REBATE.—The term 'rebate' means any discount, price concession, or fee, other than the fee described in paragraph (1)(B), the terms of which are fixed at the time of the sale and disclosed, but which is not received at the time of the sale.''.

SEC. 4. APPLICABILITY OF PRE-LIST PRICE REDUCTION AMP TO MEDICAID MINIMUM REBATE AMOUNTS.

Section 1927(c) of the Social Security Act (42 U.S.C. 1396r–8(c)) is amended—

(1) in paragraph (1)(A), in the matter preceding clause (i), by inserting ''and paragraph (5)'' after ''paragraph (2)'';

(2) in paragraph (3)(A), in the matter preceding clause (i), by inserting ''and paragraph (5)'' after ''subparagraph (C)''; and

(3) by adding at the end the following new paragraph:

''(5) SPECIAL RULE FOR DETERMINING MINIMUM BASIC REBATES FOR INSULIN.—

"(A) IN GENERAL.—In determining the amount of the rebate specified in this subsection for a dosage form and strength of a covered outpatient drug described in subparagraph (B) for any rebate period occurring after April 30, 2020, paragraph (1)(A)(ii)(II) or paragraph (3)(A)(i) (as applicable) shall be applied by substituting—

"(i) the pre-reduction average manufacturer price (as defined in subparagraph (C)) for the dosage form and strength of the drug for the rebate period; for

"(ii) the average manufacturer price for the dosage form and strength of the drug for the rebate period.

"(B) DRUGS DESCRIBED.—A covered outpatient drug is described in this subparagraph for a rebate period if the drug is insulin for which, throughout such rebate period, the manufacturer has certified the list price for each dosage form and strength of such drug in accordance with section 5(b) of the Insulin Price Reduction Act.

"(C) PRE-REDUCTION AVERAGE MANUFACTURER PRICE.—For purposes of this para-

graph, the term 'pre-reduction average manufacturer price' means, with respect to each dosage form and strength of a covered outpatient drug described in subparagraph (B) and a rebate period—

"(i) the average manufacturer price for such drug for the calendar quarter beginning July 1, 2019; increased by

"(ii) the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 2019.".

SEC. 5. LIST PRICE DATA SUBMISSIONS.

(a) INITIAL SUBMISSION.—

(1) IN GENERAL.—Not later than April 30, 2020, any manufacturer of insulin wishing to receive certification under this section shall submit to the Secretary—

(A) data on the list price of any insulin manufactured by the manufacturer during the period beginning on January 1, 2000 (or the first date on which such manufacturer begins

manufacturing such insulin) through the list price applicable at the time of the report; and

(B) a certification that such data is accurate.

(2) LATER SUBMISSIONS.—Any manufacturer of insulin that does not submit the information described in paragraph (1) by the date described in such paragraph may later submit the information described in subparagraphs (A) and (B) of paragraph (1) to the Secretary. Such a manufacturer who submits such information pursuant to this paragraph is eligible to certify its list price for the applicable insulin under subsection (b)(2)(A)(ii) with respect to the first plan year that begins at least 15 months after the date of submission under this paragraph.

(b) ANNUAL PRICE CERTIFICATION.—

(1) IN GENERAL.—Any manufacturer of insulin who submits information in accordance with subsection (a) is eligible for certification under this subsection.

(2) REQUIREMENTS.—

(A) FIRST CERTIFICATION.—

(i) INITIAL ELIGIBILITY FOR CERTIFICATION.—A manufacturer of insulin who

submits information under subsection (a)(1) is considered certified under this subsection for plan year 2022 if such manufacturer, not later than September 30, 2020, submits to the Secretary a certification that the manufacturer reduced its list price for insulin to an amount that is no greater than the list price for the same insulin that applied as of July 1, 2006.

(ii) LATER CERTIFICATION.—A manufacturer of insulin that submitted information under subsection (a)(2) not later than September 30 of the calendar year that is 2 years prior to the applicable plan year, is considered certified under this subsection for the applicable plan year if such manufacturer submits to the Secretary a certification, not later than September 30 of such calendar year, that the manufacturer reduced its list price for insulin to the amount that is no greater than the list price for the same insulin that applied as of July 1, 2006, increased by not more than the rate by which the medical care component of the consumer price index for

all urban consumers (U.S. city average) increased between September 30, 2020 and the date on which the certification is submitted.

(B) SUBSEQUENT CERTIFICATION.—For plan year 2023 and each plan year thereafter, a manufacturer of insulin who previously submitted a certification under clause (i) or (ii) of subparagraph (A) is considered certified under this subsection for the applicable plan year if such manufacturer submits, not later than September 30 of the calendar year that is 2 years prior to the applicable plan year, a certification that the manufacturer did not increase the list price for insulin previously certified under clause (i) or (ii) of subparagraph (A), by more than the rate by which the medical care component of the consumer price index for all urban consumers (U.S. city average) increased since the initial certification under such clause (i) or (ii).

(3) SPECIAL RULE FOR CERTAIN INSULIN.—

(A) IN GENERAL.—In the case of a manufacturer of insulin that did not manufacture a particular insulin in 2006, such manufacturer

may be certified under this subsection with respect to such insulin by submitting information under paragraph (2)(A) certifying that the list price of such insulin is no greater than the weighted average list price, in 2006, of, as applicable—

(i)(I) all short-acting insulins;

(II) all rapid-acting insulins; or

(III) all long-acting insulins; or

(ii) such other insulin categories, as the Secretary determines appropriate.

(B) INCREASE.—The weighted averages under subparagraph (A) shall be increased in accordance with paragraph (2)(A)(ii), as applicable.

(4) APPLICATION TO AUTHORIZED GENERIC INSULIN.—In the case of an insulin that is classified as an authorized generic drug, as defined in section 505(t)(3) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355(t)(3)), the manufacturer of such insulin may be certified under this section by submitting information under paragraph (1)(A) certifying that the list price of such authorized generic insulin is no greater than the list price, as of July 1, 2006, of the listed drug insulin product upon

which the authorized generic drug was based under section 505(t) of the Federal Food, Drug and Cosmetic Act. The certification pursuant to this paragraph applies only to the authorized generic drug insulin, and does not apply with respect to the applicable listed drug insulin.

(c) AUDITS AND PENALTIES.—The Inspector General of the Department of Health and Human Services may audit the financial records and other relevant records of any manufacturer submitting data under subsections (a) and (b), and any manufacturer or officer, director, agent, or managing employee of such manufacturer that knowingly submits false or incomplete data shall be subject to a civil penalty for each insulin for which false or incomplete data are submitted in an amount not to exceed the greater of—

(1) an amount equal to 2 times the total amount of rebates paid by the manufacturer to State Medicaid plans for the insulin for rebate periods occurring in calendar year 2018 under section 1927 of the Social Security Act (42 U.S.C. 1396r–8); or

(2) an alternative amount to be determined by the Secretary.

(d) DEFINITIONS.—In this section—

(1) the term ''insulin'' means any insulin product approved by the Food and Drug Administration to improve glycemic control in patients with diabetes mellitus;

(2) the term ''list price'' has the meaning given the term ''wholesale acquisition cost'' in section 1847A(c)(6)(B) of the Social Security Act (42 U.S.C. 1395w–3a(c)(6)(B)); and

(3) the term ''Secretary'' means the Secretary of Health and Human Services.