

116TH CONGRESS
1ST SESSION

S. 2199

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

IN THE SENATE OF THE UNITED STATES

JULY 22, 2019

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 Finance

A BILL

To provide 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.**

4 This Act may be cited as the “Insulin Price Reduc-

5 tion Act”.

6 **SEC. 2. INSULIN PRICE PROTECTIONS.**

7 (a) IN GENERAL.—Subpart II of part A of title
8 XXVII of the Public Health Service Act (42 U.S.C.
9 300gg–11 et seq.) is amended by adding at the end the
10 following:

1 **“SEC. 2729A. INSULIN PRICE PROTECTIONS.**

2 “(a) CONTRACTING REQUIREMENTS.—

3 “(1) IN GENERAL.—

4 “(A) REQUIREMENT.—Except as provided
5 in subparagraph (B), a group health plan or a
6 health insurance issuer offering group or indi-
7 vidual health insurance coverage shall not, and
8 shall ensure that any entity that provides phar-
9 macy benefits management services under a
10 contract with any such health plan or health in-
11 surance coverage does not, directly or indirectly,
12 receive from a manufacturer of certified insulin
13 a rebate, reduction in price, or other remunera-
14 tion with respect to such insulin received by an
15 enrollee in the plan or coverage and covered by
16 the plan or coverage.

17 “(B) EXCEPTION.—The requirement under
18 subparagraph (A) shall not apply to—

19 “(i) any such reduction in price that
20 is reflected at the point of sale to the en-
21 rollee; or

22 “(ii) any remuneration that is a flat
23 fee-based service fee that a manufacturer
24 of such insulin pays to a pharmacy benefit
25 manager for services rendered to the man-
26 ufacturer that relate to arrangements by

1 the pharmacy benefit manager to provide
2 pharmacy benefit management services to
3 a health plan or health insurance issuer, if
4 certain conditions established by the Sec-
5 retary are met, including requirements
6 that the fees are transparent to the health
7 plan or health insurance issuer.

8 “(2) APPLICABILITY.—The restriction under
9 paragraph (1) shall apply with respect to insulin de-
10 scribed in paragraph (1), for which the manufac-
11 turer has certified the list price in accordance with
12 section 5(b) of the Insulin Price Reduction Act with
13 respect to—

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

17 “(B) each subsequent plan year during
18 which the manufacturer limits any increase in
19 the list price to the price that gave rise to the
20 restriction under paragraph (1), adjusted by
21 not more than the price change in the medical
22 care component of the consumer price index for
23 all urban consumers (U.S. city average), as cer-
24 tified under section 5(b)(2)(B) of the Insulin
25 Price Reduction Act.

1 “(b) DEDUCTIBLE LIMITATION.—A group health
 2 plan or a health insurance issuer offering group or indi-
 3 vidual health insurance coverage shall not apply any de-
 4 ductible amount that otherwise is applicable to prescrip-
 5 tion drugs with respect to coverage of certified insulin
 6 under such plan or coverage, during the period described
 7 in subsection (a)(2).

8 “(c) HOLD HARMLESS.—In the first 2 plan years
 9 during which paragraph (1) applies with respect to an in-
 10 sulin certified under section 5(b) of the Insulin Price Re-
 11 duction Act, a group health plan or a health insurance
 12 issuer offering group or individual health insurance cov-
 13 erage shall not, and shall ensure that any entity that pro-
 14 vides pharmacy benefits management services under a
 15 contract with such health plan or health insurance cov-
 16 erage does not—

17 “(1) remove such insulin from the formulary
 18 applicable to the plan or coverage;

19 “(2) impose higher cost-sharing with respect to
 20 such insulin than the cost-sharing that applied with
 21 respect to the insulin in the year in which the list
 22 price reduction certification was provided under sec-
 23 tion 5(b)(2)(A) of the Insulin Price Reduction Act;

24 “(3) impose any prior authorization require-
 25 ments for coverage of such insulin that were not ap-

1 plied during the year in which the list price reduc-
2 tion certification was provided under such section
3 5(b)(2)(A); or

4 “(4) establish a step therapy requirement for
5 such insulin that was not applied during the year in
6 which the list price reduction certification was pro-
7 vided under such section 5(b)(2)(A).

8 “(d) DEFINITIONS.—In this section—

9 “(1) the term ‘certified insulin’ means, with re-
10 spect to a year, insulin that has been certified under
11 section 5(b) of the Insulin Price Reduction Act for
12 the year;

13 “(2) the term ‘insulin’ means any insulin prod-
14 uct approved by the Food and Drug Administration
15 to improve glycemic control in patients with diabetes
16 mellitus;

17 “(3) the term ‘list price’ has the meaning given
18 the term ‘wholesale acquisition cost’ in section
19 1847A(c)(6)(B) of the Social Security Act; and

20 “(4) the term ‘rebate’ means any discount,
21 price concession, or fee, other than the fee described
22 in section (a)(1)(B), the terms of which are fixed at
23 the time of the sale and disclosed, but which is not
24 received at the time of the sale.”.

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

6 “(D) SAFE HARBOR FOR ABSENCE OF DE-
 7 DUCTIBLE FOR INSULIN.—A plan shall not fail
 8 to be treated as a high deductible health plan
 9 by reason of exempting insulin from any de-
 10 ductible pursuant to section 2729A(b) of the
 11 Public Health Service Act during the period de-
 12 scribed in section 2729A(a)(2) of such Act.”.

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

16 **SEC. 3. INSULIN PRICE PROTECTIONS UNDER MEDICARE**
 17 **PART D.**

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

20 (1) by redesignating the subsection (m) as
 21 added by section 6063(c) of the SUPPORT for Pa-
 22 tients and Communities Act (Public Law 115–271)
 23 as subsection (n); and

24 (2) by adding at the end the following new sub-
 25 section:

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

3 “(1) LIMITATION.—

4 “(A) IN GENERAL.—Subject to subpara-
5 graphs (B) and (C), for plan year 2022 and
6 subsequent plan years, a PDP sponsor and a
7 Medicare Advantage organization shall ensure
8 that each prescription drug plan or MA–PD
9 plan offered by the sponsor or organization, and
10 any entity that provides pharmacy benefits
11 management services under a contract with the
12 prescription drug plan or MA–PD plan offered
13 by the sponsor or organization, does not, di-
14 rectly or indirectly, receive from a manufacturer
15 of certified insulin a rebate, reduction in price,
16 or other remuneration with respect to certified
17 insulin that is covered by the plan.

18 “(B) EXCEPTION.—The requirement under
19 subparagraph (A) shall not apply to—

20 “(i) any such reduction in price that
21 is reflected at the point of sale to the bene-
22 ficiary; or

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

1 macy benefit manager for services rendered
 2 to the manufacturer that relate to arrange-
 3 ments by the pharmacy benefit manager to
 4 provide pharmacy benefit management
 5 services to a prescription drug plan or
 6 MA–PD plan, if certain conditions estab-
 7 lished by the Secretary are met, including
 8 requirements that the fees are transparent
 9 to the prescription drug plan or MA–PD
 10 plan.

11 “(C) HOLD HARMLESS FOR FIRST 2 YEARS
 12 THAT AN INSULIN IS CERTIFIED.—In the first
 13 2 plan years during which paragraph (2) ap-
 14 plies with respect to a certified insulin, a PDP
 15 sponsor and a Medicare Advantage organization
 16 shall not, and shall ensure that any entity that
 17 provides pharmacy benefits management serv-
 18 ices under a contract with such sponsor or or-
 19 ganization does not—

20 “(i) remove such insulin from the for-
 21 mulary applicable to the prescription drug
 22 plan or MA–PD plan;

23 “(ii) impose higher cost-sharing with
 24 respect to such insulin than the cost-shar-
 25 ing that applied with respect to the cer-

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

5 “(iii) impose any prior authorization
 6 requirements for coverage of the certified
 7 insulin that were not applied during the
 8 year in which the list price reduction cer-
 9 tification was provided under such section
 10 5(b)(2)(A); or

11 “(iv) establish a step therapy require-
 12 ment for the certified insulin that was not
 13 applied during the year in which the list
 14 price reduction certification was provided
 15 under such section 5(b)(2)(A).

16 “(2) DEFINITIONS.—In this section:

17 “(A) CERTIFIED INSULIN.—The term ‘cer-
 18 tified insulin’ means, with respect to a year, in-
 19 sulin that has been certified under section 5(b)
 20 of the Insulin Price Reduction Act for the year.

21 “(B) INSULIN.—The term ‘insulin’ means
 22 any insulin product approved by the Food and
 23 Drug Administration to improve glycemic con-
 24 trol in patients with diabetes mellitus.

1 “(C) LIST PRICE.—The term ‘list price’
 2 has the meaning given the term ‘wholesale ac-
 3 quisition cost’ in section 1847A(c)(6)(B).

4 “(D) REBATE.—The term ‘rebate’ means
 5 any discount, price concession, or fee, other
 6 than the fee described in paragraph (1)(B), the
 7 terms of which are fixed at the time of the sale
 8 and disclosed, but which is not received at the
 9 time of the sale.”.

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

13 Section 1927(c) of the Social Security Act (42 U.S.C.
 14 1396r–8(c)) is amended—

15 (1) in paragraph (1)(A), in the matter pre-
 16 ceding clause (i), by inserting “and paragraph (5)”
 17 after “paragraph (2)”;

18 (2) in paragraph (3)(A), in the matter pre-
 19 ceding clause (i), by inserting “and paragraph (5)”
 20 after “subparagraph (C)”;

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

23 “(5) SPECIAL RULE FOR DETERMINING MIN-
 24 IMUM BASIC REBATES FOR INSULIN.—

1 “(A) IN GENERAL.—In determining the
 2 amount of the rebate specified in this sub-
 3 section for a dosage form and strength of a cov-
 4 ered outpatient drug described in subparagraph
 5 (B) for any rebate period occurring after April
 6 30, 2020, paragraph (1)(A)(ii)(II) or paragraph
 7 (3)(A)(i) (as applicable) shall be applied by sub-
 8 stituting—

9 “(i) the pre-reduction average manu-
 10 facturer price (as defined in subparagraph
 11 (C)) for the dosage form and strength of
 12 the drug for the rebate period; for

13 “(ii) the average manufacturer price
 14 for the dosage form and strength of the
 15 drug for the rebate period.

16 “(B) DRUGS DESCRIBED.—A covered out-
 17 patient drug is described in this subparagraph
 18 for a rebate period if the drug is insulin for
 19 which, throughout such rebate period, the man-
 20 ufacturer has certified the list price for each
 21 dosage form and strength of such drug in ac-
 22 cordance with section 5(b) of the Insulin Price
 23 Reduction Act.

24 “(C) PRE-REDUCTION AVERAGE MANUFAC-
 25 TURER 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

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

3 (B) a certification that such data is accu-
 4 rate.

5 (2) LATER SUBMISSIONS.—Any manufacturer
 6 of insulin that does not submit the information de-
 7 scribed in paragraph (1) by the date described in
 8 such paragraph may later submit the information
 9 described in subparagraphs (A) and (B) of para-
 10 graph (1) to the Secretary. Such a manufacturer
 11 who submits such information pursuant to this para-
 12 graph is eligible to certify its list price for the appli-
 13 cable insulin under subsection (b)(2)(A)(ii) with re-
 14 spect to the first plan year that begins at least 15
 15 months after the date of submission under this para-
 16 graph.

17 (b) ANNUAL PRICE CERTIFICATION.—

18 (1) IN GENERAL.—Any manufacturer of insulin
 19 who submits information in accordance with sub-
 20 section (a) is eligible for certification under this sub-
 21 section.

22 (2) REQUIREMENTS.—

23 (A) FIRST CERTIFICATION.—

24 (i) INITIAL ELIGIBILITY FOR CERTIFI-
 25 CATION.—A manufacturer of insulin who

1 submits information under subsection
2 (a)(1) is considered certified under this
3 subsection for plan year 2022 if such man-
4 ufacturer, not later than September 30,
5 2020, submits to the Secretary a certifi-
6 cation that the manufacturer reduced its
7 list price for insulin to an amount that is
8 no greater than the list price for the same
9 insulin that applied as of July 1, 2006.

10 (ii) LATER CERTIFICATION.—A manu-
11 facturer of insulin that submitted informa-
12 tion under subsection (a)(2) not later than
13 September 30 of the calendar year that is
14 2 years prior to the applicable plan year,
15 is considered certified under this sub-
16 section for the applicable plan year if such
17 manufacturer submits to the Secretary a
18 certification, not later than September 30
19 of such calendar year, that the manufac-
20 turer reduced its list price for insulin to
21 the amount that is no greater than the list
22 price for the same insulin that applied as
23 of July 1, 2006, increased by not more
24 than the rate by which the medical care
25 component of the consumer price index for

1 all urban consumers (U.S. city average) in-
2 creased between September 30, 2020, and
3 the date on which the certification is sub-
4 mitted.

5 (B) SUBSEQUENT CERTIFICATION.—For
6 plan year 2023 and each plan year thereafter,
7 a manufacturer of insulin who previously sub-
8 mitted a certification under clause (i) or (ii) of
9 subparagraph (A) is considered certified under
10 this subsection for the applicable plan year if
11 such manufacturer submits, not later than Sep-
12 tember 30 of the calendar year that is 2 years
13 prior to the applicable plan year, a certification
14 that the manufacturer did not increase the list
15 price for insulin previously certified under
16 clause (i) or (ii) of subparagraph (A), by more
17 than the rate by which the medical care compo-
18 nent of the consumer price index for all urban
19 consumers (U.S. city average) increased since
20 the initial certification under such clause (i) or
21 (ii).

22 (3) SPECIAL RULE FOR CERTAIN INSULIN.—

23 (A) IN GENERAL.—In the case of a manu-
24 facturer of insulin that did not manufacture a
25 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

1 which the authorized generic drug was based under
2 section 505(t) of the Federal Food, Drug and Cos-
3 metic Act. The certification pursuant to this para-
4 graph applies only to the authorized generic drug in-
5 sulin, and does not apply with respect to the applica-
6 ble listed drug insulin.

7 (c) AUDITS AND PENALTIES.—The Inspector General
8 of the Department of Health and Human Services may
9 audit the financial records and other relevant records of
10 any manufacturer submitting data under subsections (a)
11 and (b), and any manufacturer or officer, director, agent,
12 or managing employee of such manufacturer that know-
13 ingly submits false or incomplete data shall be subject to
14 a civil penalty for each insulin for which false or incom-
15 plete data are submitted in an amount not to exceed the
16 greater of—

17 (1) an amount equal to 2 times the total
18 amount of rebates paid by the manufacturer to
19 State Medicaid plans for the insulin for rebate peri-
20 ods occurring in calendar year 2018 under section
21 1927 of the Social Security Act (42 U.S.C. 1396r–
22 8); or

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

25 (d) DEFINITIONS.—In this section—

1 (1) the term “insulin” means any insulin prod-
2 uct approved by the Food and Drug Administration
3 to improve glycemic control in patients with diabetes
4 mellitus;

5 (2) the term “list price” has the meaning given
6 the term “wholesale acquisition cost” in section
7 1847A(c)(6)(B) of the Social Security Act (42
8 U.S.C. 1395w-3a(c)(6)(B)); and

9 (3) the term “Secretary” means the Secretary
10 of Health and Human Services.

○