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(Original Signature of Member)

116TH CONGRESS
1ST SESSION

H. R. _____

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

IN THE HOUSE OF REPRESENTATIVES

Ms. DEGETTE introduced the following bill; which was referred to the
Committee on _____

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.

1 300gg–11 et seq.) is amended by adding at the end the
2 following:

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

4 “(a) CONTRACTING REQUIREMENTS.—

5 “(1) IN GENERAL.—

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

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

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

24 “(ii) any remuneration that is a flat
25 fee-based service fee that a manufacturer

1 of such insulin pays to a pharmacy benefit
2 manager for services rendered to the man-
3 ufacturer that relate to arrangements by
4 the pharmacy benefit manager to provide
5 pharmacy benefit management services to
6 a health plan or health insurance issuer, if
7 certain conditions established by the Sec-
8 retary are met, including requirements
9 that the fees are transparent to the health
10 plan or health insurance issuer.

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

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

20 “(B) each subsequent plan year during
21 which the manufacturer limits any increase in
22 the list price to the price that gave rise to the
23 restriction under paragraph (1), adjusted by
24 not more than the price change in the medical
25 care component of the consumer price index for

1 all urban consumers (U.S. city average), as cer-
2 tified under section 5(b)(2)(B) of the Insulin
3 Price Reduction Act.

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

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

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

22 “(2) impose higher cost-sharing with respect to
23 such insulin than the cost-sharing that applied with
24 respect to the insulin in the year in which the list

1 price reduction certification was provided under sec-
2 tion 5(b)(2)(A) of the Insulin Price Reduction Act;

3 “(3) impose any prior authorization require-
4 ments for coverage of such insulin that were not ap-
5 plied during the year in which the list price reduc-
6 tion certification was provided under such section
7 5(b)(2)(A); or

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

12 “(d) DEFINITIONS.—In this section—

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

17 “(2) the term ‘insulin’ means any insulin prod-
18 uct approved by the Food and Drug Administration
19 to improve glycemic control in patients with diabetes
20 mellitus;

21 “(3) the term ‘list price’ has the meaning given
22 the term ‘wholesale acquisition cost’ in section
23 1847A(c)(6)(B) of the Social Security Act; and

24 “(4) the term ‘rebate’ means any discount,
25 price concession, or fee, other than the fee described

1 in section (a)(1)(B), the terms of which are fixed at
2 the time of the sale and disclosed, but which is not
3 received at the time of the sale.”.

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

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

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

19 **SEC. 3. INSULIN PRICE PROTECTIONS UNDER MEDICARE**

20 **PART D.**

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

23 (1) by redesignating the subsection (m) as
24 added by section 6063(c) of the SUPPORT for Pa-

1 tients and Communities Act (Public Law 115–271)
2 as subsection (n); and

3 (2) by adding at the end the following new sub-
4 section:

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

7 “(1) LIMITATION.—

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

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

1 “(i) any such reduction in price that
2 is reflected at the point of sale to the bene-
3 ficiary; or

4 “(ii) any remuneration that is a flat
5 fee-based service fee that a manufacturer
6 of such certified insulin pays to a phar-
7 macy benefit manager for services rendered
8 to the manufacturer that relate to arrange-
9 ments by the pharmacy benefit manager to
10 provide pharmacy benefit management
11 services to a prescription drug plan or
12 MA–PD plan, if certain conditions estab-
13 lished by the Secretary are met, including
14 requirements that the fees are transparent
15 to the prescription drug plan or MA–PD
16 plan.

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

1 “(i) remove such insulin from the for-
2 mulary applicable to the prescription drug
3 plan or MA–PD plan;

4 “(ii) impose higher cost-sharing with
5 respect to such insulin than the cost-shar-
6 ing that applied with respect to the cer-
7 tified insulin in the year in which the list
8 price reduction certification was provided
9 under section 5(b)(2)(A) of the Insulin
10 Price Reduction Act;

11 “(iii) impose any prior authorization
12 requirements for coverage of the certified
13 insulin that were not applied during the
14 year in which the list price reduction cer-
15 tification was provided under such section
16 5(b)(2)(A); or

17 “(iv) establish a step therapy require-
18 ment for the certified insulin that was not
19 applied during the year in which the list
20 price reduction certification was provided
21 under such section 5(b)(2)(A).

22 “(2) DEFINITIONS.—In this section:

23 “(A) CERTIFIED INSULIN.—The term ‘cer-
24 tified insulin’ means, with respect to a year, in-

1 insulin that has been certified under section 5(b)
2 of the Insulin Price Reduction Act for the year.

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

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

10 “(D) REBATE.—The term ‘rebate’ means
11 any discount, price concession, or fee, other
12 than the fee described in paragraph (1)(B), the
13 terms of which are fixed at the time of the sale
14 and disclosed, but which is not received at the
15 time of the sale.”.

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

19 Section 1927(c) of the Social Security Act (42 U.S.C.
20 1396r–8(c)) is amended—

21 (1) in paragraph (1)(A), in the matter pre-
22 ceding clause (i), by inserting “and paragraph (5)”
23 after “paragraph (2)”;

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

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

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

8 “(A) IN GENERAL.—In determining the
9 amount of the rebate specified in this sub-
10 section for a dosage form and strength of a cov-
11 ered outpatient drug described in subparagraph
12 (B) for any rebate period occurring after April
13 30, 2020, paragraph (1)(A)(ii)(II) or paragraph
14 (3)(A)(i) (as applicable) shall be applied by sub-
15 stituting—

16 “(i) the pre-reduction average manu-
17 facturer price (as defined in subparagraph
18 (C)) for the dosage form and strength of
19 the drug for the rebate period; for

20 “(ii) the average manufacturer price
21 for the dosage form and strength of the
22 drug for the rebate period.

23 “(B) DRUGS DESCRIBED.—A covered out-
24 patient drug is described in this subparagraph
25 for a rebate period if the drug is insulin for

1 which, throughout such rebate period, the man-
2 ufacturer has certified the list price for each
3 dosage form and strength of such drug in ac-
4 cordance with section 5(b) of the Insulin Price
5 Reduction Act.

6 “(C) PRE-REDUCTION AVERAGE MANUFAC-
7 TURER PRICE.—For purposes of this para-
8 graph, the term ‘pre-reduction average manu-
9 facturer price’ means, with respect to each dos-
10 age form and strength of a covered outpatient
11 drug described in subparagraph (B) and a re-
12 bate period—

13 “(i) the average manufacturer price
14 for such drug for the calendar quarter be-
15 ginning July 1, 2019; increased by

16 “(ii) the percentage by which the con-
17 sumer price index for all urban consumers
18 (United States city average) for the month
19 before the month in which the rebate pe-
20 riod begins exceeds such index for Sep-
21 tember 2019.”.

22 **SEC. 5. LIST PRICE DATA SUBMISSIONS.**

23 (a) INITIAL SUBMISSION.—

24 (1) IN GENERAL.—Not later than April 30,
25 2020, any manufacturer of insulin wishing to receive

1 certification under this section shall submit to the
2 Secretary—

3 (A) data on the list price of any insulin
4 manufactured by the manufacturer during the
5 period beginning on January 1, 2000 (or the
6 first date on which such manufacturer begins
7 manufacturing such insulin) through the list
8 price applicable at the time of the report; and

9 (B) a certification that such data is accu-
10 rate.

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

23 (b) ANNUAL PRICE CERTIFICATION.—

24 (1) IN GENERAL.—Any manufacturer of insulin
25 who submits information in accordance with sub-

1 section (a) is eligible for certification under this sub-
2 section.

3 (2) REQUIREMENTS.—

4 (A) FIRST CERTIFICATION.—

5 (i) INITIAL ELIGIBILITY FOR CERTIFI-
6 CATION.—A manufacturer of insulin who
7 submits information under subsection
8 (a)(1) is considered certified under this
9 subsection for plan year 2022 if such man-
10 ufacturer, not later than September 30,
11 2020, submits to the Secretary a certifi-
12 cation that the manufacturer reduced its
13 list price for insulin to an amount that is
14 no greater than the list price for the same
15 insulin that applied as of July 1, 2006.

16 (ii) LATER CERTIFICATION.—A manu-
17 facturer of insulin that submitted informa-
18 tion under subsection (a)(2) not later than
19 September 30 of the calendar year that is
20 2 years prior to the applicable plan year,
21 is considered certified under this sub-
22 section for the applicable plan year if such
23 manufacturer submits to the Secretary a
24 certification, not later than September 30
25 of such calendar year, that the manufac-

1 turer reduced its list price for insulin to
2 the amount that is no greater than the list
3 price for the same insulin that applied as
4 of July 1, 2006, increased by not more
5 than the rate by which the medical care
6 component of the consumer price index for
7 all urban consumers (U.S. city average) in-
8 creased between September 30, 2020 and
9 the date on which the certification is sub-
10 mitted.

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

1 the initial certification under such clause (i) or
2 (ii).

3 (3) SPECIAL RULE FOR CERTAIN INSULIN.—

4 (A) IN GENERAL.—In the case of a manu-
5 facturer of insulin that did not manufacture a
6 particular insulin in 2006, such manufacturer
7 may be certified under this subsection with re-
8 spect to such insulin by submitting information
9 under paragraph (2)(A) certifying that the list
10 price of such insulin is no greater than the
11 weighted average list price, in 2006, of, as ap-
12 plicable—

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

14 (II) all rapid-acting insulins; or

15 (III) all long-acting insulins; or

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

18 (B) INCREASE.—The weighted averages
19 under subparagraph (A) shall be increased in
20 accordance with paragraph (2)(A)(ii), as appli-
21 cable.

22 (4) APPLICATION TO AUTHORIZED GENERIC IN-
23 SULIN.—In the case of an insulin that is classified
24 as an authorized generic drug, as defined in section
25 505(t)(3) of the Federal Food, Drug and Cosmetic

1 Act (21 U.S.C. 355(t)(3)), the manufacturer of such
2 insulin may be certified under this section by sub-
3 mitting information under paragraph (1)(A) certi-
4 fying that the list price of such authorized generic
5 insulin is no greater than the list price, as of July
6 1, 2006, of the listed drug insulin product upon
7 which the authorized generic drug was based under
8 section 505(t) of the Federal Food, Drug and Cos-
9 metic Act. The certification pursuant to this para-
10 graph applies only to the authorized generic drug in-
11 sulin, and does not apply with respect to the applica-
12 ble listed drug insulin.

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

23 (1) an amount equal to 2 times the total
24 amount of rebates paid by the manufacturer to
25 State Medicaid plans for the insulin for rebate peri-

1 ods occurring in calendar year 2018 under section
2 1927 of the Social Security Act (42 U.S.C. 1396r–
3 8); or

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

6 (d) DEFINITIONS.—In this section—

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

11 (2) the term “list price” has the meaning given
12 the term “wholesale acquisition cost” in section
13 1847A(c)(6)(B) of the Social Security Act (42
14 U.S.C. 1395w–3a(c)(6)(B)); and

15 (3) the term “Secretary” means the Secretary
16 of Health and Human Services.