

116TH CONGRESS  
1ST SESSION

# H. R. 4906

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

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## IN THE HOUSE OF REPRESENTATIVES

OCTOBER 29, 2019

Ms. DEGETTE (for herself and Mr. REED) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

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## 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.—During the period begin-  
12 ning on the date a certification is first made under section  
13 5(b)(2)(A) of the Insulin Price Reduction Act and ending  
14 on the last day of the second plan year beginning on or  
15 after such date, a group health plan or a health insurance  
16 issuer offering group or individual health insurance cov-  
17 erage shall not, and shall ensure that any entity that pro-  
18 vides pharmacy benefits management services under a  
19 contract with such health plan or health insurance cov-  
20 erage does not—

21 “(1) restrict or disadvantage such insulin from  
22 the formulary applicable to the plan or coverage rel-  
23 ative to any other insulin or similar formulation;

24 “(2) impose higher cost-sharing with respect to  
25 such insulin than the cost-sharing that applied with

1 respect to the insulin in the year in which the list  
2 price reduction certification was provided under sec-  
3 tion 5(b)(2)(A) of the Insulin Price Reduction Act;

4 “(3) impose any prior authorization require-  
5 ments for coverage of such insulin that were not ap-  
6 plied during the year in which the list price reduc-  
7 tion certification was provided under such section  
8 5(b)(2)(A); or

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

13 “(d) DEFINITIONS.—In this section—

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

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

22 “(3) the term ‘list price’ has the meaning given  
23 the term ‘wholesale acquisition cost’ in section  
24 1847A(c)(6)(B) of the Social Security Act; and

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

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

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

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

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

22                   **PART D.**

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

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

5           (2) by adding at the end the following new sub-  
6 section:

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

9           “(1) LIMITATION.—

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

24           “(B) EXCEPTION.—The requirement under  
25 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.

○