

116TH CONGRESS  
1ST SESSION

# H. R. 5364

To require the Secretary of Health and Human Services to establish an annual reference price for insulin products for purposes of Federal health programs, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

DECEMBER 9, 2019

Mrs. BEATTY (for herself, Mr. PAYNE, Mr. BISHOP of Georgia, Ms. NORTON, Mr. McEACHIN, Mr. CLAY, Mr. LIPINSKI, Mr. THOMPSON of Mississippi, and Mr. BROWN of Maryland) introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Armed Services, Veterans' Affairs, Oversight and Reform, and Natural Resources, 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 require the Secretary of Health and Human Services to establish an annual reference price for insulin products for purposes of Federal health programs, and for other purposes.

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 “End Price Gouging  
5       for Insulin Act”.

1 **SEC. 2. REFERENCE PRICE FOR INSULIN PRODUCTS.**

2 (a) REFERENCE PRICE.—The Secretary of Health  
3 and Human Services (referred to in this section as the  
4 “Secretary”), in accordance with subsection (b), shall es-  
5 tablish an annual reference price for insulin products.  
6 Notwithstanding any other provision of law, including sec-  
7 tion 1860D–11(i) of the Social Security Act (42 U.S.C.  
8 1395w–111(i)), with respect to enrollees or beneficiaries  
9 in any of the Federal health programs described in sub-  
10 section (c), the wholesale acquisition cost for insulin prod-  
11 ucts, including the cost-sharing amount, shall not exceed  
12 the reference price for the applicable year.

13 (b) CRITERIA.—

14 (1) IN GENERAL.—Not later than 6 months  
15 after the date of enactment of this Act and every 6  
16 months thereafter, the Secretary shall establish the  
17 reference price for insulin products—

18 (A) by determining the median wholesale  
19 acquisition cost or the commensurate list price  
20 in the reference countries for insulin products  
21 among the reference countries in which such  
22 products are available, if insulin product pricing  
23 information is available for at least three of  
24 such countries; or

25 (B) in the case that insulin product pricing  
26 information or dosage equivalents are not avail-

1           able for at least three of the reference coun-  
2           tries, by determining an appropriate price based  
3           on—

4                   (i) the clinical and therapeutic effect  
5                   and value of the product;

6                   (ii) patient access to the product;

7                   (iii) the costs associated with manu-  
8                   facturing, marketing, researching, and de-  
9                   veloping the product;

10                  (iv) total revenues, net profit, and ex-  
11                  ecutive compensation associated with the  
12                  manufacturer of the product; and

13                  (v) other factors, as the Secretary de-  
14                  termines appropriate.

15           (2) REFERENCE COUNTRIES.—For purposes of  
16           paragraph (1), the reference countries are Japan,  
17           Germany, the United Kingdom, France, Italy, Can-  
18           ada, Australia, Spain, the Netherlands, Switzerland,  
19           and Sweden.

20           (c) FEDERAL HEALTH PROGRAMS.—The reference  
21           price established under subsection (a) shall apply with re-  
22           spect to covered insulin products under—

23                   (1) the Medicare program under title XVIII of  
24                   the Social Security Act (42 U.S.C. 1395 et seq.);

1           (2) a State Medicaid plan under title XIX of  
2 the Social Security Act (42 U.S.C. 1396 et seq.);

3           (3) the State Children’s Health Insurance Pro-  
4 gram under title XXI of the Social Security Act (42  
5 U.S.C. 1397aa et seq.);

6           (4) the TRICARE program under chapter 55 of  
7 title 10, United States Code;

8           (5) hospital care and medical services furnished  
9 by the Department of Veterans Affairs under chap-  
10 ters 17 and 18 of title 38, United States Code;

11           (6) the Federal Employees Health Benefits  
12 Program established under chapter 89 of title 5,  
13 United States Code; and

14           (7) any health program, service, function, activ-  
15 ity, or facility funded, in whole or part, under the  
16 Indian Health Care Improvement Act (25 U.S.C.  
17 1601 et seq.), including through direct or contract  
18 care provided under such Act or through a contract  
19 or compact under the Indian Self-Determination and  
20 Education Assistance Act (25 U.S.C. 5304 et seq.).

21           (d) APPLICABILITY TO OTHER PURCHASERS OF IN-  
22 SULIN PRODUCTS.—Notwithstanding any other provision  
23 of law, an insulin product manufacturer shall offer such  
24 product at the reference price to all individuals, including  
25 individuals who are not insured and individuals who are

1 covered under a group health plan or group or individual  
2 health insurance coverage.

3 (e) CIVIL PENALTY.—The Secretary shall enforce  
4 this section by imposing a civil penalty upon any insulin  
5 product manufacturer who does not comply with the re-  
6 quirements of subsection (a), for each year in which the  
7 violation occurs, in an amount equal to 10 times the dif-  
8 ference between—

9 (1) the total amount received by the manufac-  
10 turer for sales of insulin products under the Federal  
11 health programs under subsection (e) for the year;  
12 less

13 (2) the total amount the manufacturer would  
14 have received for sales of insulin products under  
15 such programs for the year if the manufacturer had  
16 complied with subsection (a).

17 (f) USE OF AMOUNTS COLLECTED.—Each year, the  
18 Secretary of the Treasury shall allocate the amount col-  
19 lected under subsection (e) for the previous year as fol-  
20 lows:

21 (1) Half of such amount shall be deposited in  
22 the Federal Hospital Insurance Trust Fund and the  
23 Federal Supplementary Medical Insurance Trust  
24 Fund (including the Medicare Prescription Drug Ac-  
25 count within such Trust Fund) in such proportion

1 as the Secretary of Health and Human Services de-  
2 termines appropriate.

3 (2) Half of such amount shall be transferred to  
4 the National Institutes of Health, for purposes of  
5 carrying out drug research and development.

6 (g) APPLICABILITY TO BRAND AND GENERIC INSU-  
7 LIN PRODUCTS.—The reference price established under  
8 subsection (a) shall apply to insulin products approved  
9 under subsection (c) or (j) of section 505 of the Federal  
10 Food, Drug, and Cosmetic Act (21 U.S.C. 355) or under  
11 subsection (a) or (k) of section 351 of the Public Health  
12 Service Act (42 U.S.C. 262).

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