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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.

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.

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 "End Price Gouging for Insulin Act".

SEC. 2. REFERENCE PRICE FOR INSULIN PRODUCTS.

(a) REFERENCE PRICE.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), in accordance with subsection (b), shall establish an annual reference price for insulin products. Notwithstanding any other provision of law, including section 1860D–11(i) of the Social Security Act (42 U.S.C. 1395w–111(i)), with respect to enrollees or beneficiaries in any of the Federal health programs described in subsection (c), the wholesale acquisition cost for insulin products, including the cost-sharing amount, shall not exceed the reference price for the applicable year.

(b) CRITERIA.—

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

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

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

able for at least three of the reference countries, by determining an appropriate price based on—

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

(ii) patient access to the product;

(iii) the costs associated with manufacturing, marketing, researching, and developing the product;

(iv) total revenues, net profit, and executive compensation associated with the manufacturer of the product; and

(v) other factors, as the Secretary determines appropriate.

(2) REFERENCE COUNTRIES.—For purposes of paragraph (1), the reference countries are Japan, Germany, the United Kingdom, France, Italy, Canada, Australia, Spain, the Netherlands, Switzerland, and Sweden.

(c) FEDERAL HEALTH PROGRAMS.—The reference price established under subsection (a) shall apply with respect to covered insulin products under—

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

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

(3) the State Children's Health Insurance Program under title XXI of the Social Security Act (42 U.S.C. 1397aa et seq.);

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

(5) hospital care and medical services furnished by the Department of Veterans Affairs under chapters 17 and 18 of title 38, United States Code;

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

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

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

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

(e) CIVIL PENALTY.—The Secretary shall enforce this section by imposing a civil penalty upon any insulin product manufacturer who does not comply with the requirements of subsection (a), for each year in which the violation occurs, in an amount equal to 10 times the difference between—

(1) the total amount received by the manufacturer for sales of insulin products under the Federal health programs under subsection (c) for the year; less

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

(f) USE OF AMOUNTS COLLECTED.—Each year, the Secretary of the Treasury shall allocate the amount collected under subsection (e) for the previous year as follows:

(1) Half of such amount shall be deposited in the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund (including the Medicare Prescription Drug Account within such Trust Fund) in such proportion

as the Secretary of Health and Human Services determines appropriate.

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

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

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